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Planned caesarean section for women with a twin pregnancy

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Abstract

Background—Twin pregnancies are associated with increased perinatal mortality, mainly related to prematurity, but complications during birth may contribute to perinatal loss or morbidity. The option of planned caesarean section to avoid such complications must therefore be considered. On the other hand, randomised trials of other clinical interventions in the birth process to avoid problems related to labour and birth (planned caesarean section for breech, and continuous electronic fetal heart rate monitoring), have shown an unexpected discordance between short-term perinatal morbidity and long-term neurological outcome. The risks of caesarean section for the mother in the current and subsequent pregnancies must also be taken into account.

Objectives—To determine the short- and long-term effects on mothers and their babies, of planned caesarean section for twin pregnancy.

Search methods—We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (30 September 2011).

Selection criteria—Randomised trials comparing a policy of caesarean section with planned vaginal birth for women with twin pregnancy.

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CONTRIBUTIONS OF AUTHORS

CA Crowther prepared a previous version of this review, limited to twin pregnancies with non-vertex second twin ('Caesarean delivery for the second twin' - see Crowther 1996), and contributed to the development of this protocol and review. JF Barrett reviewed the topic, prepared a first draft of the background, and contributed to the protocol and review development. GJ Hofmeyr prepared the first draft of the protocol and of the review, and is the guarantor of the review.

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DECLARATIONS OF INTEREST

JF Barrett is principal investigator for a trial of planned caesarean section for twin pregnancy, which will be considered for inclusion. He will not participate in decisions relating to that study (Barrett 2008).

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

The methods section has been updated to reflect the Pregnancy and Childbirth Group's updated methods text and the latest Cochrane Handbook (Higgins 2011).

Data collection and analysis—Two researchers independently assessed eligibility, quality and extracted data. Data were checked for accuracy.

Main results—One small trial with unconfirmed allocation concealment compared caesarean section with planned vaginal birth in 60 women with vertex/non-vertex twin pregnancies. There were no differences in perinatal outcome. The trial was too small to exclude the possibility of clinically meaningful benefits of either approach. There is one additional trial currently ongoing.

Authors' conclusions—There is a lack of robust evidence to guide clinical advice regarding the method of birth for twin pregnancies. Women should be informed of possible benefits and risks of either approach, including short-term and long-term consequences for both mother and babies. Future research should aim to provide unbiased evidence, including long-term outcomes.

Medical Subject Headings (MeSH)

*Pregnancy Outcome; *Pregnancy; Twin; Cesarean Section [adverse effects; *methods]

MeSH check words

Female; Humans; Pregnancy

BACKGROUND

Twin pregnancy results from one of two distinct biological processes. The more common process is fertilisation of more than one ovum following multiple ovulation. Here the offspring may be of the same gender or not, are genetically no more similar than siblings, and have separate placental circulations and gestational sacs (dizygotic, diamniotic, dichorionic). The less common process is splitting of a single developing embryo. The offspring are of the same gender and genetically identical. The degree of separation depends on the developmental stage at which the separation takes place, and can be anything from separate circulations (monozygotic, dichorionic, diamniotic) to conjoined twins.

The incidence of monozygotic twins is fairly constant, but that of dizygotic twins varies considerably between communities and families, and has recently increased in many well-resourced health services because of the use of fertility treatments and assisted conception and the increase in the number of older aged mothers (Anonymous 2000; Laws 2010; Wilcox 1996). The rate of multiple birth varies from country to country. In Canada, the rate of multiple births increased from 1.9% in 1981 to 2.5% in 1997 (Anonymous 2000; Joseph 2001a). In Australia, the rate in 2008 was 3.1% of all births (Laws 2010).

Over 97% of all multiple pregnancies are twin pregnancies (Joseph 1998). Approximately 40% of twins present as vertex/vertex, 35% as vertex/non-vertex and the remaining 25% of twins present with the leading baby in a non-vertex presentation at birth (Blickstein 1987; Grisaru 2000).

Mortality and morbidity for twins versus singletons

Infants from a twin pregnancy are at a higher risk of perinatal/neonatal mortality than infants from a singleton pregnancy (Cheung 2000; Fabre 1988; Ghai 1988; Joseph 2001b; Kiely

1990; Lie 2000). Some of this is due to a higher risk of preterm birth (Joseph 2001b). However, even among twin babies that are greater than 2500 g at birth, there is a higher risk of death than among singletons of the same birthweight. Again, the absolute rates of perinatal mortality and morbidity will vary by population. In Australia, the perinatal death rate for twins for 2008 was 6.8 times higher and for higher multiple births 18.1 times higher than for singleton births (Laws 2010). Kiely 1990 reviewed the data on 16,831 multiple births from the New York City Department of Health's computerised vital records for the period 1978 to 1984. The perinatal mortality rate for twins versus singletons at 2501 to 3000 g was 4.3/1000 versus 3.8/1000 (risk ratio (RR) 1.12) and at 3001 g or more, 7.4/1000 versus 2.2/1000 (RR 3.32), respectively. The intrapartum fetal death rate for twins versus singletons at 2501 to 3000 g was 1.22/1000 versus 0.34/1000 (RR 3.54; 95% confidence interval (CI) 1.82 to 6.88). Other studies have confirmed this higher risk of fetal and neonatal death in twins versus singletons if the pregnancy is at or near term or above 2500 g in birthweight (Cheung 2000; Fabre 1988; Ghai 1988; Lie 2000). Neonatal seizures, respiratory morbidity, and low Apgar scores at one and five minutes have also been shown to be higher for twins versus singleton infants at birthweights greater than 1500 g and greater than 3000 g (Ghai 1988).

Some of the higher risk of adverse perinatal outcome in twins compared with singletons may be due to restricted fetal growth which, in turn, may result in a higher risk of adverse events occurring during pregnancy, during labour or during birth. The higher risk may be due to trauma and asphyxia associated with the birth of the second twin. It is possible that some of these adverse outcomes may be avoided by an appropriately timed delivery by caesarean section (CS). The timing of birth for women with a twin pregnancy is the subject of another Cochrane review (Dodd 2003). In a multicentre randomised controlled trial comparing planned CS and planned vaginal birth (VB) for the singleton breech fetus at term, planned CS reduced the risk of perinatal death or serious neonatal morbidity three-fold (from 5.0% to 1.6%, P less than 0.001) (Hannah 2000). Although some of the deaths in the planned VB group in this study were due to difficulties associated with the actual birth, some were associated with problems that occurred during labour. Thus, a policy of planned CS may be beneficial for women with a pregnancy at risk of complications during labour because it reduces the exposure of the pregnancy to labour.

Evidence of benefits and risks related to planned CS for twins

Outcome for second twin compared with first twin—In a study of 1305 twin pairs at 1500 g or more birthweight delivered between 1988 and 1999 in Nova Scotia, the risk of adverse perinatal outcome (intrapartum fetal death, neonatal death, moderate-severe respiratory distress syndrome (RDS), asphyxia, trauma and complications of prematurity) was significantly increased for second-born compared with first-born twins (RR 2.1; 95% CI 1.4 to 3.1) (Persad 2001b). However, it should be noted that in the Term Breech Trial, short-term neonatal morbidity was not associated with any long-term impairment (Whyte 2004).

There is also evidence that the second twin is at greater risk of adverse perinatal outcome, compared to the first twin if delivery is vaginal but the same has not been shown if delivery is by CS. Arnold and colleagues undertook a matched case-control study of preterm twin

pairs (Arnold 1987). The risk of RDS was increased for the second twin compared to the first if delivery was vaginal (odds ratio (OR) 14.2; 95% CI 2.5 to 81.1) but not if delivery was by CS (OR 0.90; 95% CI 0 to 17.8). This could be due to a greater protective effect of VB for the leading twin.

Outcomes for twins born vaginally versus by CS—Higher rates of adverse perinatal outcome have been reported for the twin pregnancy at or near term if birth is vaginal versus by CS (Barrett 2004). In the Kiely 1990 review, for twins in vertex presentation weighing more than 3000 g at birth, the perinatal mortality rate was 12.3/1000 versus 2.9/1000 (RR 4.22) if birth was vaginal versus by CS. However, comparisons of actual as opposed to planned method of delivery are subject to considerable bias. In a retrospective study of women with previous CS and current twin pregnancy, perinatal mortality was more common following trial of labour than repeat CS, but there was no difference in outcome after adjusting for confounding variables (Aaronson 2010).

There is increasing evidence for perinatal benefits related to vaginal birth. In a cross-sectional study of 6929 inborn infants without congenital anomalies, with gestational ages from 37 to 41 (6/7) weeks with vertex presentation, non-urgent caesarean delivery under regional anaesthesia compared to vaginal delivery under local or no anaesthesia increased the risk of bag and mask ventilation (OR 1.42, 95% CI 1.07 to 1.89) when adjusted for number of gestations, maternal hypertension and birthweight (De Almeida 2010). However, another retrospective study found no significant increase in transient tachypnoea of the newborn associated with increasing rates of elective CS for twin pregnancies over time (Suzuki 2010).

In a retrospective study of twin births at 37 or more weeks' gestation, elective but not emergency CS was associated with an increased risk of transfusion in the neonate (Suzuki 2008).

Outcomes for twins delivered by planned VB (actual VB plus emergency CS) versus planned CS—A systematic review of non-randomised studies that compared the policies of planned VB and planned CS for the delivery of twins weighing at least 1500 g or reaching at least 32 weeks' gestation (Hogle 2002) found four small studies that were eligible for inclusion in the review (Blickstein 2000; Grisaru 2000; Rabinovici 1987; Wells 1991). A meta-analysis of the data from the four studies did not find significant differences between the two approaches to delivery in terms of mortality or neonatal morbidity, although low Apgar score at five minutes was reduced with a policy of CS. This finding, however, was confined to twins in which the first twin presented as a breech. A subsequent retrospective comparison of planned vaginal birth versus planned CS for twin pregnancies with a leading breech found no significant differences in perinatal or maternal morbidity, other than an increase in thromboembolic disease in the planned CS group (Sentilhes 2007). Two large retrospective studies of women with previous CS and current twin pregnancy comparing planned vaginal birth with elective CS (Ford 2006; Varner 2005), found no difference in maternal or perinatal outcome, other than an incidence of uterine rupture of 0.9% in the planned vaginal birth group in one study (Ford 2006).

A comparison of outcomes in two Danish counties with high (57%) and low (28%) caesarean rates for twin pregnancy found no difference in perinatal outcomes (Henriksen 1994).

The previously published Cochrane review (Crowther 1996) found only one randomised controlled trial of planned CS versus planned VB for twins, in which 60 pairs of twins were enrolled (Rabinovici 1987). There were no perinatal deaths or cases of serious neonatal morbidity in either group. The sample size was too small to provide evidence of the better approach to delivery.

In low-resourced settings with limited facilities and personnel for CSs, high post-CS complication rates and uncertain access for the mother to CS facilities in future pregnancies, the benefit to the mother of avoiding CS is greater than in well-resourced settings.

Outcomes for second twin born by CS following vaginal birth of twin one, compared with CS birth of both twins—

A prospective multicentre cohort study compared the outcome for second twins born by CS following vaginal birth of twin one, compared with CS for both twins. There was no difference in low Apgar scores, low cord blood pH nor neonatal encephalopathy. Neonatal infection was increased in the group with CS following vaginal birth of twin one, but this difference was not statistically significant after logistic regression analysis (Alexander 2008). In a large retrospective study of planned vaginal birth for twin pregnancies, CS for the second twin occurred in 9% of cases and was more common when the presentation of the second twin was nonvertex, and in pregnancies with other complications, and less common when the vaginal birth of the first twin was operative (Wen 2004a).

Importance of fetal presentation—If the first twin presents as breech, the current trend in well-resourced health systems, as for singleton breech presentation, is to recommend CS as being safer for the babies. This approach may be influenced by extrapolation of evidence from randomised trials of planned CS for singleton breech presentation (Hofmeyr 2003), though the interpretation of this evidence is the subject of considerable debate. The approach to the delivery of vertex/nonvertex twins is controversial (ACOG 2002; Barrett 2000; Crowther 1996). For twins presenting vertex/vertex, most clinicians recommend planned VB (ACOG 2002; Crowther 1996). However, planned CS may benefit twins in which the first twin is presenting vertex for a number of reasons. As many as 20% of vertex presenting second twins will change presentation spontaneously after the first twin is delivered (Houlihan 1996). A substantial number of those presenting vertex/vertex will present with serious acute intrapartum problems following the delivery of the first twin (for example, conversion to transverse lie, cord prolapse, prolonged interval to delivery of the second twin), which may lead to emergency CS, perinatal death, and neonatal morbidity. Lastly, if there are benefits to avoiding labour, both twins regardless of presentation should benefit.

Maternal outcomes—A policy of planned VB for women with a twin pregnancy in a hospital setting is associated with a 30% to 40% rate of emergency CS. Among those twins in which the first twin is born vaginally, there is still a risk of emergency CS for the birth of the second twin, ranging from 4% (Suzuki 2009) to 7% (Persad 2001a). In a retrospective

case-control study, the risk of CS for the second twin after vaginal birth of the first was increased in association with a history of infertility therapy, gestational age equal to or greater than 39 weeks, non-vertex presentation, operative delivery of the first twin and intertwin delivery time interval greater than 30 minutes (Suzuki 2009). As the risk of maternal death is highest if delivery is by emergency CS, lowest following a VB, and intermediate following an elective CS (Hall 1999), increasing numbers of emergency CS may reduce the mortality benefits of planned VBs.

A relatively small case control study found no increased maternal morbidity for CS for twin compared with singleton pregnancy (Simoes 2007). However, in a large population-based, matched case-control study using the United Kingdom Obstetric Surveillance System, the risk of peripartum hysterectomy was increased for women with twin pregnancy (OR 6.30, 95% CI 1.73 to 23.0) (Knight 2008), while another study found twin pregnancy to be a risk factor for post CS wound sepsis (Schneid-Kofman 2005). There is growing evidence of an association between VB and urinary incontinence, particularly if the VB requires forceps or vacuum extraction (Farrell 2001; Meyer 1998; Wilson 1996). Urinary incontinence identified in the postpartum period has been shown to have long-lasting effects, with a high risk of urinary incontinence five years later (Viktrup 2001). Use of the supine position for birth has been cited as a possible contributor to incontinence following vaginal birth. Faecal incontinence and incontinence off latus have been reported to be associated with VB, particularly if forceps are used, and if there are lacerations involving the anal sphincter (Eason 2002; Zetterström 1999).

In the Term Breech Trial, there was no significant difference in maternal mortality or immediate serious maternal morbidity between planned CS and planned VB for singleton breech presentation at term (3.9% versus 3.2%, $P = 0.35$) (Hannah 2002). At three months postpartum, the women in the planned CS group reported a lower incidence of urinary incontinence (4.5% versus 7.3%, $P = 0.02$). Although the incidence of incontinence of flatus was not different between groups, if incontinence of flatus was reported, it was significantly less of a problem in the planned CS group ($P = 0.006$). At two years, the only significant difference found was less constipation in the planned vaginal birth group (Hofmeyr 2003). However, long-term risks of CS, particularly risks in subsequent pregnancies such as placenta praevia, placenta accreta, repeat CS and uterine rupture, as well as reduced fertility, have not been evaluated in randomised trials. Thus from a maternal perspective, the relative benefits and risks of planned CS versus planned VB are not clear-cut. Any evaluation of risks versus benefits must take into account the likelihood of serious long-term adverse effects of CS. Data from a large Canadian cohort indicated that even in women with previous CS, maternal mortality was significantly higher with CS than with VB after CS (Wen 2004b).

Given that in well-resourced environments suicide is becoming an important contributor to maternal mortality, emotional consequences of birth such as depression need to be given importance when weighing up benefits and harms of different approaches to care. Even when emergency CS is performed, some women may gain self-esteem from having at least attempted to achieve VB. The sense of control from participation in the decision-making process may also promote self-esteem.

A more detailed account of evidence related to the benefits and risks of caesarean section is given in Lavender 2006.

For these reasons, a systematic review of the information from randomised trials is required to determine the relative benefits and risks of planned CS for twin pregnancy, for the infants and the mother.

OBJECTIVES

To assess, from the best available evidence, the effects on mortality and morbidity for mother and baby, of a policy of planned caesarean section versus planned vaginal birth for twin pregnancy.

METHODS

Criteria for considering studies for this review

Types of studies—All comparisons of intention to perform caesarean section and intention to birth vaginally, subject to a management protocol, for women with a twin pregnancy at or before term; random allocation to treatment and control groups, with adequate allocation concealment; violations of allocated management and exclusions after allocation not sufficient to materially affect outcomes.

Types of participants—Women with viable twin pregnancy considered suitable for vaginal birth, excluding women with known serious fetal anomaly.

Types of interventions—Planned caesarean section compared with planned vaginal birth subject to the requirements of a management protocol.

Types of outcome measures

Primary outcomes

- Perinatal or neonatal death (excluding fatal anomalies) or serious neonatal morbidity (e.g. severe birth asphyxia, seizures, neonatal encephalopathy, serious birth trauma, severe RDS, prolonged neonatal intensive care unit admission; or as defined by trial authors);
- perinatal or infant death (excluding fatal anomalies) or disability in childhood;
- maternal death or serious maternal morbidity (e.g. admission to intensive care unit, septicaemia, organ failure, uterine rupture, hysterectomy, major surgical complication, life-threatening event, long-term disability, or as defined by trial authors).

Secondary outcomes

Short-term perinatal/neonatal morbidity

1. Perinatal/neonatal death (excluding fatal anomalies);

2. serious neonatal morbidity (e.g. seizures, birth asphyxia as defined by trial authors, neonatal encephalopathy, birth trauma);
3. Apgar score less than seven at five minutes;
4. Apgar score less than four at five minutes;
5. low cord blood pH as defined by trial authors;
6. high cord blood base deficit as defined by trial authors;
7. neonatal intensive care unit admission;
8. neonatal encephalopathy, as defined by trial authors;
9. birth trauma, as defined by trial authors;
10. nerve palsy (including brachial plexus injury);
11. subdural or intracerebral haemorrhage;
12. intraventricular haemorrhage: grade III or IV;
13. cystic periventricular leukomalacia;
14. septicaemia;
15. meningitis;
16. necrotising enterocolitis;
17. chronic lung disease;
18. assisted ventilation 24 hours or more.

Long-term infant outcomes

19. Death (excluding fatal anomalies);
20. disability in childhood, as defined by trial authors;
21. medical problems.

Short-term maternal outcomes

22. Caesarean section;
23. regional analgesia;
24. general anaesthesia;
25. instrumental vaginal delivery;
26. death;
27. serious maternal morbidity (e.g. intensive care unit admission, septicaemia, organ failure; or as defined by trial authors);
28. intraoperative organ damage;
29. deep vein thrombosis;

30. pulmonary embolism;
31. wound sepsis;
32. systemic infection;
33. disseminated intravascular coagulation;
34. amniotic fluid embolism;
35. postpartum haemorrhage, as defined by the trial authors;
36. postpartum anaemia, as defined by trial authors;
37. blood transfusion;
38. uterine rupture;
39. repeat surgery;
40. hysterectomy;
41. wound infection;
42. prolonged hospital stay;
43. woman not satisfied with care.

Longer-term maternal outcomes (at one to six months)

44. Breastfeeding failure, as defined by trial authors;
45. perineal pain;
46. abdominal pain;
47. backache or back pain;
48. any pain;
49. dyspareunia, as defined by trial authors;
50. uterovaginal prolapse;
51. urinary incontinence;
52. flatus incontinence;
53. faecal incontinence;
54. postnatal depression, as defined by trial authors;
55. postnatal self-esteem, as defined by trial authors;
56. postnatal anxiety, as defined by trial authors;
57. relationship with baby, as defined by trial authors;
58. relationship with partner, as defined by trial authors;
59. quality of life.

Long-term maternal outcomes (at more than one year)

- 60. Breastfeeding failure, as defined by trial authors;
- 61. perineal pain;
- 62. abdominal pain;
- 63. backache or back pain;
- 64. any pain;
- 65. dyspareunia, as defined by trial authors;
- 66. uterovaginal prolapse;
- 67. urinary incontinence;
- 68. flatus incontinence;
- 69. faecal incontinence;
- 70. infertility;
- 71. subsequent pregnancy;
- 72. miscarriage or termination of a subsequent pregnancy;
- 73. caesarean section in a subsequent pregnancy;
- 74. uterine rupture in a subsequent pregnancy;
- 75. dysmenorrhoea;
- 76. menorrhagia;
- 77. postnatal depression, as defined by trial authors;
- 78. postnatal self-esteem, as defined by trial authors;
- 79. postnatal anxiety, as defined by trial authors;
- 80. quality of life;
- 81. relationship with child, as defined by trial authors;
- 82. relationship with partner, as defined by trial authors.

Health services

- 83. Caregiver not satisfied;
- 84. cost.

We have included outcomes 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 a format suitable for analysis.

We have reported only outcomes with data available in the analysis tables.

Search methods for identification of studies

Electronic searches—We contacted the Trials Search Co-ordinator to search the Cochrane Pregnancy and Childbirth Group's Trials Register (30 September 2011).

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.

We did not apply any language restrictions.

Data collection and analysis

Selection of studies—Two review authors independently assessed for inclusion all the potential studies we identified as a result of the search strategy. We planned to resolve any disagreement through discussion or, if required, we would have consulted a third person.

Data extraction and management—We designed a form to extract data. For eligible studies, two review authors extracted the data using the agreed form. We would resolve discrepancies through discussion or, if required, we would consult a third person. We entered data into Review Manager software (RevMan 2011) and checked for accuracy.

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

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

(1) Random sequence generation (checking for possible selection bias): We described for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. We assessed the method as:

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

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

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

(3) Blinding of participants, personnel and outcome assessment (checking for possible performance bias or detection bias): We described for each included study the methods used, if any, to blind study participants, personnel or outcome assessors from knowledge of which intervention a participant received. We considered that studies were at low risk of bias if they were blinded, or if we judged that the lack of blinding would be unlikely to affect results. We assessed blinding separately for different outcomes or classes of outcomes.

We assessed the methods as:

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

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data): We described for each included study, and for each outcome or class of outcomes, the completeness of data including attrition and exclusions from the analysis. We stated whether attrition and exclusions were reported and the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes.

Where sufficient information was reported, or could be supplied by the trial authors, we re-included missing data in the analyses which we undertook.

We assessed methods as:

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

(5) Selective reporting (checking for reporting bias): We described for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We assessed the methods as:

- low risk of bias (where it is clear that all of the study's 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 described for each included study any important concerns we had about other possible sources of bias.

We assessed 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 made explicit judgements about whether studies were at high risk of bias, according to the criteria given in the *Handbook* (Higgins 2011). With reference to (1) to (6) above, we assessed the likely magnitude and direction of the bias and whether we considered it was likely to impact on the findings. We planned to 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 presented results as summary risk ratio with 95% confidence intervals.

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

Unit of analysis issues

Cluster-randomised trials: We would include cluster-randomised trials in the analyses along with individually randomised trials. We would adjust their sample sizes using the methods described in the *Handbook* using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible), from a similar trial or from a study of a similar population. If we used ICCs from other sources, we would report this and conduct sensitivity analyses to investigate the effect of variation in the ICC. If we identified both cluster-randomised trials and individually-randomised trials, we planned to synthesise the relevant information. We would consider it reasonable to combine the results from both if there is little heterogeneity between the study designs and the interaction between the effect of intervention and the choice of randomisation unit is considered to be unlikely.

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

Crossover trials: Not applicable.

Other unit of analysis issues: For maternal outcomes we used the number of mothers as the denominator. For neonatal outcomes, we used the number of babies as the denominator. If information on ICC was available, we would use cluster trial methods with each woman regarded as a randomised cluster. In the absence of information on ICC, we analysed the results of babies as if individually randomised, conceding that the width of the confidence interval might be under-estimated.

Dealing with missing data—For included studies, we noted levels of attrition. We would 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 carried out analyses, as far as possible, on an intention-to-treat basis, i.e. we attempted to include all participants randomised to each group in the analyses, and all participants were 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 was the number randomised minus any participants whose outcomes were known to be missing.

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

Assessment of reporting biases—If there had been 10 or more studies in the meta-analysis we would have investigated reporting biases (such as publication bias) using funnel

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

Data synthesis—We carried out statistical analysis using the Review Manager software (RevMan 2011). We would use fixed-effect meta-analysis for combining data where it was reasonable to assume that studies were estimating the same underlying treatment effect: i.e. where trials were examining the same intervention, and we judged the trials' populations and methods to be sufficiently similar. If there was clinical heterogeneity sufficient to expect that the underlying treatment effects differ between trials, or if substantial statistical heterogeneity was detected, we would use random-effects meta-analysis to produce an overall summary if an average treatment effect across trials was considered clinically meaningful. We would treat the random-effects summary as the average range of possible treatment effects and we would discuss the clinical implications of treatment effects differing between trials. If the average treatment effect was not clinically meaningful we would not combine trials. If we used random-effects analyses, we would present the results 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 identified substantial heterogeneity, we would investigate it using subgroup analyses and sensitivity analyses. We would consider whether an overall summary was meaningful, and if it was, use random-effects analysis to produce it.

We planned to carry out the following subgroup analyses.

1. Settings with high (more than 20 per 1000) versus low (less than 20 per 1000) perinatal mortality versus perinatal mortality mixed or unknown.
2. Leading twin cephalic versus non-cephalic versus mixed presentation or unknown.
3. Leading twin cephalic and second twin cephalic versus non-cephalic versus mixed presentation or unknown.
4. Gestational age term versus preterm versus mixed or unknown gestational age.

We would use all outcomes in subgroup analysis.

For fixed-effect Mantel-Haenszel meta-analyses we would assess differences between subgroups by interaction tests. For random-effects and fixed-effect meta-analyses using methods other than Mantel-Haenszel, we would assess differences between subgroups by inspection of the subgroups' confidence intervals; non-overlapping confidence intervals would indicate a statistically significant difference in treatment effect between the subgroups.

Sensitivity analysis—We would undertake sensitivity analyses to assess the effect of exclusion of studies with high risk of bias.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies. Three studies were identified. We included one trial (Rabinovici 1987), one trial is ongoing (Barrett 2008) and one trial is awaiting assessment (Dera 2009). See 'Characteristics of included studies; Characteristics of studies awaiting classification; Characteristics of ongoing studies'.

Included studies—We included one trial (Rabinovici 1987), involving 60 women with cephalic/non-cephalic twin pregnancies in labour at 35 or more weeks' gestation who were allocated to vaginal delivery (33) or caesarean section (CS) (27). The trial was conducted in Israel. In the vaginal delivery group, two women were delivered by CS, and in four the second twin changed to cephalic presentation. These six women were excluded from the published data analysis. We have included the categorical neonatal outcomes in this review to conform to an intention-to-treat analysis. We were not able to include the continuous neonatal variables, and the maternal outcomes for the six excluded women were not reported, so we have not included these outcomes in this review. The reported maternal febrile morbidity (excluding the six women) was increased in the CS group (11/27 versus 3/27).

Risk of bias in included studies

Allocation—The allocation procedure was described as being changed randomly by a non-involved person without prior notice on a time basis. A 20% difference in group sizes was not accounted for (27 versus 33). The possibility of inadequate allocation concealment is therefore high.

Blinding—Blinding not feasible and therefore the trial was rated as 'high risk' of bias. There was no mention about whether neonatal assessments were blinded.

Incomplete outcome data—The trial was assessed as 'high risk' for attrition bias. Six women allocated to planned vaginal birth were excluded from primary analysis for delivery (this was not in accordance with the protocol) (2 CS and 4 vertex vaginal births). Analysis was not conducted on an intention-to-treat basis.

Selective reporting—No pre-published protocol available to check predefined outcome reporting.

Other potential sources of bias—We assessed Rabinovici 1987 as being at 'high risk' for other bias because of a baseline imbalance: CS $n = 27$ versus vaginal $n = 33$.

Effects of interventions

There were no differences in perinatal outcomes between the groups (perinatal or neonatal death, serious neonatal morbidity, Apgar score less than seven at five minutes, Apgar score less than four at five minutes, neonatal encephalopathy, birth trauma, nerve palsy (including

brachial plexus injury), subdural or intracerebral haemorrhage, intraventricular haemorrhage: grade III or IV). However, the study was underpowered to exclude the possibility of clinically meaningful differences.

DISCUSSION

The potential effects of the choice of planned mode of delivery in specific clinical circumstances are complex, and extend beyond the easily measurable clinical outcomes, to less obvious consequences such as emotional effects on the mother, her sense of self-esteem and her relationship with her child or children. Previous large randomised trials of interventions associated with more medical intervention in the birth process, which have included long-term follow-up of the children, have shown unexpected discordance between short-term perinatal morbidity and long-term neurodevelopmental outcomes. Two examples are planned caesarean section (CS) for term breech presentation, and continuous electronic fetal monitoring and scalp blood sampling during labour.

In the Term Breech Trial, in countries with low perinatal mortality rates, there were three perinatal deaths and 26 babies with severe perinatal morbidity of 511 in the planned vaginal birth group, compared with no deaths and severe perinatal morbidity in two of 514 babies following planned CS (Hannah 2000). One would have expected less neurodevelopmental delay at two years in the planned CS group, but the trend (though not statistically significant) was in the opposite direction: 12/457 compared with 7/463 in the planned vaginal birth group (Whyte 2004).

In the Dublin trial of continuous cardiotocography during labour, neonatal seizures occurred in 12 of 6530 babies following continuous electronic monitoring during labour, and 27 of 6554 following intermittent auscultation (Macdonald 1985). There were 14 perinatal deaths in each group. Despite there being far fewer cases of neonatal seizures in the continuous electronic monitoring group, the rate of subsequent cerebral palsy was similar between groups: 12/6527 versus 10/6552 respectively (Grant 1989). Similar comparisons in the Seattle trial of continuous electronic monitoring and scalp blood sampling for preterm labour were: seizures 7/122 versus 7/124 (Luthy 1987); cerebral palsy 16/82 versus 7/91 respectively (Shy 1990).

Because of this consistent trend to more long-term neurological sequelae following medical interventions during childbirth than would be expected on the basis of the short-term perinatal outcomes, clinical decisions must be based on long-term rather than short-term outcomes. As more data relevant to this review become available, it is important that the implications of short-term perinatal morbidity be interpreted with caution, and the results of long-term follow up be awaited.

AUTHORS' CONCLUSIONS

Implications for practice

There are insufficient data from randomised trials to be sure of the relative benefits and risk of planned caesarean section for twin pregnancies. Women should be informed of possible

risks during labour and vaginal birth pertinent to their specific clinical presentation, as well as the beneficial perinatal effects of labour and vaginal birth, and the current and long-term effects of caesarean section for both mother and babies. Medical interventions in the birth process should be avoided unless there is reasonable clinical certainty that they will be of long-term benefit.

Implications for research

There is need for robust evidence from large randomised trials on the long-term effects on mother and babies, of planned caesarean section for twin pregnancy.

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SOURCES OF SUPPORT

Internal sources

- (GJH) Effective Care Research Unit, University of the Witwatersrand, University of Fort Hare, Eastern Cape Department of Health, South Africa.

External sources

- (GJH) HRP-UNDP/UNFPA/WHO/World Bank Special Programme in Human Reproduction, Geneva, Switzerland.
- National Institute for Health Research, UK.

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

Appendix

CHARACTERISTICS OF STUDIES

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

Rabinovici 1987

Methods	'Randomized control trial.'
Participants	Inclusion criteria: twin pregnancy, induced or spontaneous labour, both alive. 1st vertex, 2nd breech or transverse, 35-42 weeks estimated gestational age, no known fetal anomaly, no signs of acute placental insufficiency or abruption, normal amniotic fluid volume, normal FHR testing, no maternal or obstetric indications for a specific route of delivery, cervix < 7 cm dilated
Interventions	Experimental intervention: planned lower segment caesarean section, preferably with epidural analgesia, but dependent on preference of anaesthetist Control/comparison intervention: planned vaginal birth following evaluation of labour progress using 'Friedman curve'; continuous electronic fetal monitoring of both babies; lie of 2nd twin confirmed clinically or with ultrasound; if breech, assisted breech delivery planned; of fetal distress or poor progress despite oxytocin, total breech extraction done; artificial rupture of second sac as late as possible; if second twin in oblique or transverse lie, internal version and complete breech extraction under general analgesia or epidural analgesia if in place; routine episiotomy

Outcomes	Method of delivery; birthweights, Apgar scores, neonatal and maternal complications	
Notes	Setting: Chaim Sheba Medical Centre labour ward.	
Risk of bias		
<i>Bias</i>	Authors‘ judgement	Support for judgement
Random sequence generation (selection bias)	Unclear risk	Allocation “changed randomly by a non-involved person without prior notice on a time basis”. 20% difference in group sizes not accounted for (27 vs 33)
Allocation concealment (selection bias)	High risk	See above.
Blinding (performance bias and detection bias) All outcomes	High risk	Blinding not feasible. Not mentioned whether neonatal assessments blinded
Incomplete outcome data (attrition bias) All outcomes	High risk	6 women allocated to planned vaginal birth excluded from primary analysis for delivery not according to protocol (2 CS and 4 vertex vaginal births). Analysis was not conducted on an intention-to-treat basis. Only categorical data included as data given separately for the 6 excluded women could be added to the primary data
Selective reporting (reporting bias)	Unclear risk	No pre-published protocol available to check predefined outcome reporting
Other bias	High risk	Baseline imbalance: CS n = 27 vs vaginal n = 33.

CS: caesarean section

FHR: fetal heart rate

vs: versus

Characteristics of studies awaiting assessment [ordered by study ID]

Dera 2009

Methods	'Randomized'.
Participants	Women with twin pregnancy 32 to 38 weeks 6 days.
Interventions	Planned caesarean section vs planned vaginal birth.
Outcomes	No data given in published abstract.
Notes	Full report awaited.

vs: versus

Characteristics of ongoing studies [ordered by study ID]

Barrett 2008

Trial name or title	Twin birth study.
Methods	Randomized trial.

Participants	Women with twin pregnancy at 32 to 38 weeks, both babies alive, estimated weights 1500 g to 4000 g, leading twin vertex presentation, diamniotic, no lethal fetal anomalies, no contraindication to labour or vaginal birth
Interventions	Planned caesarean section vs planned vaginal birth.
Outcomes	Primary: perinatal or neonatal mortality or neonatal morbidity, excluding lethal congenital abnormalities. Secondary: death or poor neurodevelopmental outcome at 2 years of age; problematic urinary or fecal/flatus incontinence for the mother at 3 months and 2 years postpartum; maternal death or severe morbidity; maternal satisfaction at 3 months; breastfeeding at 3 months; maternal quality of life and depression at 3 months and 2 years; costs
Starting date	December 2003.
Contact information	Barrett J, Sunnybrook Health Services Centre, Toronto, Canada
Notes	Sample size 1400.

DATA AND ANALYSES

Comparison 1 Planned caesarean section versus planned vaginal birth

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Maternal death or serious maternal morbidity	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 Perinatal or neonatal death	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Serious neonatal morbidity	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Apgar score less than seven at five minutes < eight	1	120	Risk Ratio (M-H, Fixed, 95% CI)	1.22 [0.18, 8.39]
5 Apgar score less than four at five minutes < five	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
6 Neonatal encephalopathy, as defined by trial authors	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
7 Birth trauma, as defined by trial authors	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
8 Nerve palsy (including brachial plexus injury)	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
9 Subdural or intracerebral haemorrhage	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
10 Intraventricular haemorrhage: grade III or IV	1	120	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
11 Short-term maternal outcomes: caesarean section	1	60	Risk Ratio (M-H, Fixed, 95% CI)	13.36 [4.05, 44.09]
12 Short-term maternal outcomes: mortality	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]
13 Short-term maternal outcomes: serious maternal morbidity	1	60	Risk Ratio (M-H, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 1 Maternal death or serious maternal morbidity

Review: Planned caesarean section for women with a twin pregnancy

Comparison: 1 Planned caesarean section versus planned vaginal birth

Outcome: 1 Maternal death or serious maternal morbidity

Analysis 1.2

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 2 Perinatal or neonatal death

Review: Planned caesarean section for women with a twin pregnancy

Comparison: 1 Planned caesarean section versus planned vaginal birth

Outcome: 2 Perinatal or neonatal death

Analysis 1.3

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 3 Serious neonatal morbidity

Review: Planned caesarean section for women with a twin pregnancy
 Comparison: 1 Planned caesarean section versus planned vaginal birth
 Outcome: 3 Serious neonatal morbidity

Analysis 1.4

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 4 Apgar score less than seven at five minutes < eight

Review: Planned caesarean section for women with a twin pregnancy
 Comparison: 1 Planned caesarean section versus planned vaginal birth
 Outcome: 4 Apgar score less than seven at five minutes < eight

Analysis 1.5

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 5 Apgar score less than four at five minutes < five

Review: Planned caesarean section for women with a twin pregnancy

Comparison: 1 Planned caesarean section versus planned vaginal birth

Outcome: 5 Apgar score less than four at five minutes < five

Analysis 1.6

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 6 Neonatal encephalopathy, as defined by trial authors

Review: Planned caesarean section for women with a twin pregnancy

Comparison: 1 Planned caesarean section versus planned vaginal birth

Outcome: 6 Neonatal encephalopathy as defined by trial authors

Analysis 1.7

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 7 Birth trauma, as defined by trial authors

Review: Planned caesarean section for women with a twin pregnancy

Comparison: 1 Planned caesarean section versus planned vaginal birth

Outcome: 7 Birth trauma, as defined by trial authors

Analysis 1.8

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 8 Nerve palsy (including brachial plexus injury)

Review: Planned caesarean section for women with a twin pregnancy

Comparison: 1 Planned caesarean section versus planned vaginal birth

Outcome: 8 Nerve palsy (including brachial plexus injury)

Analysis 1.9

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 9 Subdural or intracerebral haemorrhage

Review: Planned caesarean section for women with a twin pregnancy

Comparison: 1 Planned caesarean section versus planned vaginal birth

Outcome: 9 Subdural or intracerebral haemorrhage

Analysis 1.10

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 10 Intraventricular haemorrhage: grade III or IV

Review: Planned caesarean section for women with a twin pregnancy

Comparison: 1 Planned caesarean section versus planned vaginal birth

Outcome: 10 Intraventricular haemorrhage: grade III or IV

Analysis 1.11

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 11 Short-term maternal outcomes: caesarean section

Review: Planned caesarean section for women with a twin pregnancy

Comparison: 1 Planned caesarean section versus planned vaginal birth

Outcome: 11 Short-term maternal outcomes: caesarean section

Analysis 1.12

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 12 Short-term maternal outcomes: mortality

Review: Planned caesarean section for women with a twin pregnancy

Comparison: 1 Planned caesarean section versus planned vaginal birth

Outcome: 12 Short-term maternal outcomes: mortality

Analysis 1.13

Comparison 1 Planned caesarean section versus planned vaginal birth, Outcome 13 Short-term maternal outcomes: serious maternal morbidity

Review: Planned caesarean section for women with a twin pregnancy
 Comparison: 1 Planned caesarean section versus planned vaginal birth
 Outcome: 13 Short-term maternal outcomes: serious maternal morbidity

HISTORY

Protocol first published: Issue 2, 2007

Review first published: Issue 12, 2011

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* Indicates the major publication for the study

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PLAIN LANGUAGE SUMMARY

Planned caesarean section for a twin pregnancy

The incidence of twins varies considerably between communities and families and has recently increased because of the number of older mothers and the use of fertility treatments and assisted conception. Infants from a twin pregnancy are at a higher risk of death around the time of birth than are infants from a singleton pregnancy. Some of this is due to a higher risk of preterm birth. The second-born twin has an increased risk of a poor perinatal outcome compared with the first-born twin.

A policy of planned vaginal birth for women with a twin pregnancy in a hospital setting is associated with a 30% to 40% rate of emergency caesarian section. Among those twins in which the first twin is born vaginally, there is still a risk of emergency section for the birth of the second twin. It is possible that some of the adverse outcomes may be avoided by appropriately timed delivery by caesarean section but the risks of caesarean section for the mother in the current and subsequent pregnancies must be taken into account.

In this review we identified only one small trial with unconfirmed allocation concealment that randomly assigned the women to planned caesarean section or planned vaginal birth. The 60 women were in labour at 35 or more weeks' gestation with the leading twin cephalic and the second twin non-cephalic. The perinatal outcome was similar between the two groups and the trial was too small to exclude the possibility of clinically meaningful benefits of either approach. There is very little clear research evidence to provide guidance on the method of birth for twin pregnancies. The benefits and risks should be made available to women, including short-term and long-term consequences for both mother and babies. Future research should aim to provide more clarity on this issue as medical interventions in the birth process should be avoided unless there is reasonable clinical certainty that they will be of long-term benefit.