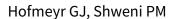


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[Intervention Review]

Symphysiotomy for feto-pelvic disproportion

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ABSTRACT

Background

Symphysiotomy is an operation in which the fibres of the pubic symphysis are partially divided to allow separation of the joint and thus enlargement of the pelvic dimensions during childbirth. It is performed with local analgesia and does not require an operating theatre nor advanced surgical skills. It may be a lifesaving procedure for the mother or the baby, or both, in several clinical situations. These include: failure to progress in labour when caesarean section is unavailable, unsafe or declined by the mother; and obstructed birth of the aftercoming head of a breech presenting baby. Criticism of the operation because of complications, particularly pelvic instability, and as being a 'second best' option has resulted in its decline or disappearance from use in many countries. Several large observational studies have reported high rates of success, low rates of complications and very low mortality rates.

Objectives

To determine, from the best available evidence, the effectiveness and safety of symphysiotomy versus alternative options for obstructed labour in various clinical situations.

Search methods

We searched the Cochrane Pregnancy and Childbirth Group's Trials Register (7 July 2012).

Selection criteria

Randomized trials comparing symphysiotomy with alternative management, or alternative techniques of symphysiotomy, for obstructed labour or obstructed aftercoming head during breech birth.

Data collection and analysis

Planned methods included evaluation of studies against objective quality criteria for inclusion, extraction of data, and analysis of data using risk ratios or mean differences with 95% confidence intervals. The primary outcomes were maternal death or severe morbidity, and perinatal death or severe morbidity.

Main results

We found no randomized trials of symphysiotomy.



Authors' conclusions

Because of controversy surrounding the use of symphysiotomy, and the possibility that it may be a life-saving procedure in certain circumstances, professional and global bodies should provide guidelines for the use (or non-use) of symphysiotomy based on the best available evidence (currently evidence from observational studies). Research is needed to provide robust evidence of the effectiveness and safety of symphysiotomy compared with no symphysiotomy or comparisons of alternative symphysiotomy techniques in clinical situations in which caesarean section is not available; and compared with caesarean section in clinical situations in which the relative risks and benefits are uncertain (for example in women at very high risk of complications from caesarean section).

PLAIN LANGUAGE SUMMARY

Symphysiotomy for feto-pelvic disproportion

Symphysiotomy is an operation to enlarge the capacity of the mother's pelvis by partially cutting the fibres joining the pubic bones at the front of the pelvis. Usually, when the baby is too big to pass through the pelvis, a caesarean section is performed. If caesarean section is not available, or the mother is too ill for, or refuses, caesarean section or if there is insufficient time to perform caesarean section (for example when the baby's body has been born feet first, and the head is stuck), symphysiotomy may be performed. Local anaesthetic solution is injected to numb the area, then a small cut is made in the skin with a scalpel, and most of the fibres of the symphysis are cut. As the baby is born, the symphysis separates just enough to allow the baby through. Large observational studies have shown that symphysiotomy is extremely safe with respect to life-threatening complications, but rarely may result in pelvic instability. For this reason, and because the operation is viewed as a 'second-class' operation, it is seldom performed today. Health professionals fear censure should they perform a symphysiotomy which leads to complications. Proponents argue that many deaths of mothers and babies from obstructed labour in parts of the world without caesarean section facilities could be prevented if symphysiotomy was used. This review found no randomized trials evaluating symphysiotomy.



BACKGROUND

Introduction

Symphysiotomy is an operation in which fibres of the pubic symphysis pubis are divided with a scalpel using local analgesic infiltration. This allows the pubic bones to separate, creating more space in the pelvis for the birth of the baby.

Symphysiotomy has come to be regarded as an unacceptable operation because of perceptions that it is a gruesome procedure which may result in an unstable pelvic girdle and urinary incontinence, and the view that it is a 'second-class' operation used only in women from poor communities (Verkuyl 2007). In the last 20 years it has virtually disappeared from practice in many low-income countries. An article referring to symphysiotomy and pubiotomy (division of the pubic bone) in Irish women in the 1950s as 'barbaric' (Payne 2001) provoked considerable debate. Emotions, and sensitivity to political correctness make it difficult to reach an objective evaluation of the benefits and risks of symphysiotomy.

When caesarean section is not available or not safe or unacceptable to the mother, symphysiotomy may be life-saving for both mother and baby (Wykes 2003). Complications of the procedure have been reduced by improved operative techniques (Maharaj 2002) (such as partial rather than complete symphysiotomy) and postoperative care (early mobilisation).

Possible indications for symphysiotomy

The main indications for symphysiotomy are cephalo-pelvic disproportion with cephalic presentation, including cases of failed assisted birth, and arrested aftercoming head of the breech (Sunday-Adeoye 2004). It has been recommended for shoulder dystocia unresponsive to conventional procedures (Baxley 2004; Kwek 2006), but one report of three cases of symphysiotomy as a last resort for shoulder dystocia recorded poor results (Goodwin 1997), and this indication is controversial. Symphysiotomy may be lifesaving for women too ill to survive caesarean section following neglected labour (Maharaj 2002; Verkuyl 2001). Women from some cultural backgrounds are immovably opposed to caesarean section, but will accept symphysiotomy because it does not contradict their cultural imperative to give birth vaginally.

Apart from the use of symphysiotomy to overcome existing obstruction, the availability of symphysiotomy may influence obstetric choices. For example, caesarean section may be chosen for breech birth because of the possibility of difficult vaginal birth in a small proportion of cases. If the mother and caregivers feel reassured that the problem of obstruction to the aftercoming head can if necessary be overcome with symphysiotomy, then routine caesarean section can be avoided in a large number of cases, whereas symphysiotomy will be required in only a very small number in which the problem actually occurs, if at all. Availability of symphysiotomy as an option in a health service may encourage attendance by women who avoid the service because of a wish to avoid caesarean section.

Advantages and disadvantages

Symphysiotomy has several advantages over caesarean section:

- 1. it is more rapid to perform;
- 2. it is simpler;

- 3. it can be performed by health workers without formal training in laparotomy skills;
- 4. only local analgesia is used;
- 5. no operating theatre, anaesthetist, electricity or sophisticated equipment are needed;
- there is no risk of scarred uterus in subsequent pregnancies, particularly when women may not in future have ready access to caesarean section;
- 7. it may be life-saving for the breech baby with entrapped aftercoming head, and possibly in shoulder dystocia;
- it may be preferred in cultures in which caesarean section is viewed as a personal failure on the part of the woman (Maharaj 2002);
- 9. it results in a permanent enlargement of the pelvis (Ersdal 2008);
- 10. use of symphysiotomy reduces the caesarean section rate (Nkwo 2009).

Disadvantages include:

- 1. for birth of the baby the cervix must be fully dilated or progress to full dilatation;
- it is contraindicated in the presence of gross disproportion, e.g. in hydrocephaly;
- 3. it may rarely be associated with morbidity such as pelvic pain and instability (Chalidis 2007);
- 4. other complications include vaginal lacerations; haematuria (blood in the urine); wound infection; urinary incontinence; and vesico-vaginal fistula (a track between the bladder and the vagina). Necrosis of the urethra and bladder neck have been described following symphysiotomy, though the fact that in all cases the baby had died prior to the procedure suggested that pressure necrosis from prolonged obstructed labour may have been the cause (Onsrud 2008).

Symphysiotomy in practice - results of observational studies

The core issue regarding the use of symphysiotomy is the possibility of long-term morbidity.

In a report of 32 women having a symphysiotomy from Mozambique and Botswana, with follow up on 31 (Bergstrom 1994), immediate complications were vaginal lacerations (three), haematuria (one), wound infection (one) and pain causing gait problems (two). There were no cases of persistent pain or other complications at follow up.

A review and report of 54 additional women from Tanzania concluded that symphysiotomy is associated with lower mortality than caesarean section and similar rates of complications (though different complications) (Van Roosmalen 1987).

A small follow-up study in Zimbabwe found no difference in long-term morbidity between women who had symphysiotomy compared with Caesarean section for similar indications (Ersdal 2008).

A retrospective comparison of 65 women having a symphysiotomy and 108 having a caesarean section performed in 1988 to 1994 after a failed trial of assisted birth at the Port Moresby General Hospital (Papua New Guinea) revealed no significant differences in perinatal or maternal outcomes (Mola 1995). Mothers who had



symphysiotomy required a longer hospital stay, but had fewer complications necessitating additional surgery. The authors cited as the main complications of symphysiotomy: leg and pelvic pain, pelvic instability, and stress incontinence.

A recent review of 5000 cases of symphysiotomy in the last century concluded: "... symphysiotomy is safe for the mother from a vital perspective, confers a permanent enlargement of the pelvis and facilitates vaginal birth in future pregnancies, and is a life saving operation for the child. Severe complications are rare. ... [T]here is considerable evidence to support a reinstatement of symphysiotomy in the obstetric arsenal, for the benefit of women in obstructed labour and their offspring" (Bjorklund 2002). The commentary on the latter paper calls for symphysiotomy to be made widely available in order to reduce the appalling rate of death and morbidity from obstructed labour which persists in poor countries (Liljestrand 2002).

Subsequent reports of case series of symphysiotomy have also concluded that the procedure has few complications. A report from Nigeria documented 1013 symphysiotomies performed between 1982 and 1999 (3.7% of 27,477 births) (Sunday-Adeoye 2004). Indications included cephalopelvic disproportion (88%), arrest of the aftercoming head of the breech and previous caesarean section with mild cephalopelvic disproportion. Postoperative complications (36) included failed symphysiotomy (10), transient pelvic and leg pain (12), transient stress incontinence (6), paraurethral lacerations (vaginal tears alongside the urethra) (3), vaginal lacerations (2), gait abnormality (2) and vesico-vagina fistula (successfully repaired) (1). There were 104 perinatal deaths and one maternal death from pulmonary embolism three days after birth.

A report from Mile Four Mission Hospital, Abakaliki, Nigeria, made the point that caesarean section was viewed culturally as a reproductive failure. During 2000 and 2001, 75 of 4596 women (1.6%) gave birth with partial symphysiotomy. There were 11 complications, including paraurethral lacerations (four), and transient stress incontinence (four) wound infection (two) and haemorrhage (one). All the women could walk and run at follow up (Ezegwui 2004).

There have been case reports from well-resourced countries, when symphysiotomy has been used, for example, for birth of the aftercoming head of a breech presenting baby (Wykes 2003). The place of symphysiotomy in well-resourced countries has recently been addressed (Menticoglou 2009).

Recent guidelines issued by the Society of Obstetricians and Gynecologists of Canada recommend the use of symphysiotomy for obstructed aftercoming head of the breech (Kotaska 2009).

The importance of proper training has been emphasised (Verkuyl 2008).

A survey in Zimbabwe found that doctors and midwives working in peripheral district hospitals had more positive attitudes towards symphysiotomy than those working in central hospitals (Ersdal 2008).

The contention that symphysiotomy is an unacceptable operation has seldom been based on the views of clients. A Nigerian survey of pregnant women's views in a region where symphysiotomy has been practised for many years and is well know among women found that 63% of women given the choice would prefer symphysiotomy to caesarean section (Onah 2004).

Setting-specific questions regarding symphysiotomy

There are two questions regarding the appropriateness of use of symphysiotomy.

First: are there clinical situations in which symphysiotomy is preferable to caesarean section or other conventional methods? This is a straightforward clinical issue.

The second is more complex: when caesarean section is not available, should symphysiotomy be used as a 'second best' option?

To place the second question in context, we need to consider the question of maternal mortality related to obstructed labour. The Millenium Development Goals call for a reduction in maternal mortality ratio by 75% between 1990 and 2015. In many low-income countries, maternal mortality ratios are in the region of 1000 per 100,000 births. One of the major causes is obstructed labour. For example, in a retrospective analysis of births at Jimma hospital, south western Ethiopia from September 1990 to May 1999, 7% (945/13,425) were complicated by obstructed labour. Maternal case mortality rate from obstructed labour was 9.1% and perinatal mortality rate 62.1%. Obstructed labour was the commonest cause of maternal and perinatal mortality at the hospital during the study period, being responsible for 45.5% and 37.4% of the deaths respectively (Gaym 2002).

A hospital-based review of 86 maternal deaths (580/100,000 births) between 1981 and 1986 in Pondicherry, India, found the following causes which may be related to obstructed labour: prolonged labour 8.1%; ruptured uterus 9.3%; sepsis other than post-abortion sepsis 11.8%; haemorrhage 8.1%. Most of the women who died were illiterate (97.6%), poor (98.8%), and had received no prenatal care (94.2%), and 47.7% travelled more than 60 km to the hospital. Untrained attendants had excessively interfered with about 33% before they reached the hospital (Rajaram 1995).

Vesico-vaginal and recto-vaginal fistulas (open channels from the bladder or rectum to the vagina) remain an enormous problem in many poor countries, most being the result of prolonged obstructed labour (Steiner 1996).

Caesarean section for treatment of obstructed labour is often unavailable or unacceptable in poor countries. When it is available, lack of facilities and skills often result in an operative mortality in the region of 1%. For example, in a Nigerian study, the caesarean section rate in Ile-Ife increased from 2.3% in 1977 to 10.6% in 1985 due to a higher proportion of cephalopelvic disproportion (39.9%). Morbidity occurred in 33% and mortality in 0.71% of caesarean sections (Okonofua 1988). In a study in seven rural district hospitals in Zimbabwe, the post-caesarean section maternal mortality was 1.6%, mainly from haemorrhage (Van Eygen 2008). Maternal and perinatal morbidity from caesarean section may be particularly high when performed in the second stage of labour with the baby's head deeply impacted in the mother's pelvis and reduced amniotic fluid volume. In this situation the relative benefits of symphysiotomy may be more pronounced.



A crucial question to be answered if maternal mortality from obstructed labour in poor countries is to be taken seriously, is whether symphysiotomy is an effective and acceptable strategy to use. If so, considerable influence from governments and health organizations will be needed to implement the practice and to overcome current negative sentiments towards it.

Symphysiotomy technique

See Appendix 1.

Need for a review

There is a need to evaluate the available evidence, and if necessary recommend further research, regarding the following questions.

What are the relative risks and benefits of symphysiotomy for:

- 1. obstructed aftercoming head during breech birth;
- 2. shoulder dystocia;
- 3. obstructed labour when no caesarean section facilities are available;
- 4. compared with caesarean section in specific circumstances such as a mother who is not fit for anaesthesia, or who prefers symphysiotomy.

OBJECTIVES

To determine, from the best available evidence, the relative benefits and risks of symphysiotomy in defined clinical situations, compared with alternative management; and the relative benefits and risks of alternative symphysiotomy techniques.

METHODS

Criteria for considering studies for this review

Types of studies

Randomized controlled trials. We planned to include quasirandomized trials, as well as studies presented only as abstracts, provided adequate details were available.

Types of participants

Women in labour for whom symphysiotomy is a possible option, including the following clinical situations:

- 1. suspected cephalopelvic disproportion in first stage of labour;
- suspected cephalopelvic disproportion in second stage of labour;
- 3. suspected cephalopelvic disproportion, baby demised (versus caesarean section or craniotomy);
- 4. suspected cephalopelvic disproportion, caesarean section contraindicated, refused or not available;
- 5. failed vacuum or forceps birth;
- 6. arrested aftercoming head during breech birth;
- 7. shoulder dystocia unresponsive to conservative manoeuvres.

Cephalopelvic disproportion is typically suspected when labour fails to progress in spite of adequate uterine contractions, usually with signs of obstruction such as excessive moulding of the baby's head and caput succedaneum.

Types of interventions

Symphysiotomy compared with alternative technique of symphysiotomy or alternative management, including:

- 1. caesarean section;
- 2. other obstetric procedures;
- 3. allowing more time for labour to progress;
- 4. augmentation of labour;
- transfer to health centre with more advanced facilities (e.g. for caesarean section);
- 6. destructive procedures (e.g. craniotomy).

Types of outcome measures

Primary outcomes

- 1. Maternal death or severe morbidity (8, 10, 11 below)
- 2. Perinatal death or severe morbidity (4, 5, 7 below)

Secondary outcomes

For the mother

- 1. Postoperative pain
- 2. Blood loss
- 3. Blood transfusion
- 4. Vesico-vaginal fistula
- 5. Anaemia
- 6. Sepsis
- 7. Repeat surgery
- 8. Venous thromboembolism
- 9. Intensive care unit (ICU) admission
- 10. Duration of hospital admission
- 11.Long-term severe pain
- 12.Long-term difficulty walking
- 13. Urinary incontinence
- 14. Flatus incontinence
- 15. Faecal incontinence
- 16. Breastfeeding failure (as defined by trial authors)
- 17.Depression
- 18. Satisfaction with care
- 19.Preference
- 20. Subsequent infertility or obstetric problems
- 21.Perinatal death

For the baby

- 1. Low five-minute Apgar score (as defined by trial authors)
- 2. Low cord blood pH or high base deficit (as defined by trial authors)
- 3. Injury
- 4. Admission to neonatal ICU
- 5. Neonatal encephalopathy
- 6. Duration of hospitalisation
- 7. Neurological deficit (as defined by trial authors)
- 8. Death



For the caregivers/facility

- 1. Caregiver satisfaction
- 2. Cost

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 (7 July 2012).

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

- quarterly searches of the Cochrane Central Register of Controlled Trials (CENTRAL);
- 2. weekly searches of MEDLINE;
- 3. weekly searches of EMBASE;
- handsearches of 30 journals and the proceedings of major conferences;
- 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 Coordinator searches the register for each review using the topic list rather than keywords.

We did not apply any language restrictions.

Data collection and analysis

No randomized or quasi-randomized trials were identified. In future updates of this review, if more data become available, the methods to be used for data collection and analysis are outlined in Appendix 2.

RESULTS

Description of studies

We found no randomized or quasi-randomized trials of symphysiotomy for either inclusion or exclusion.

Risk of bias in included studies

No studies included.

Effects of interventions

No studies included.

DISCUSSION

Symphysiotomy is a controversial procedure. It is regarded by many as an outdated and even unacceptable operation. On the other hand it is claimed to be a life-saving procedure in certain clinical situations (such as obstructed aftercoming head during breech birth), and in settings with no access to caesarean section, for wider indications such as obstructed labour. In the absence of information from randomized trials, policy and clinical decisions regarding the use of symphysiotomy need to be based on evidence from observational studies as outlined in the introduction.

AUTHORS' CONCLUSIONS

Implications for practice

In view of the emotive debates surrounding the use of symphysiotomy, and the likelihood that use of symphysiotomy may be lifesaving in several clinical circumstances, while awaiting results of future high quality trials, it is important for professional and global bodies to produce guidelines based on objective evaluation of available evidence. Such guidelines should take into account the current appalling maternal and perinatal mortality rates from obstructed labour in communities where safe caesarean section is not available or is unacceptable.

Implications for research

There is a need for randomized trials to evaluate the effectiveness and safety of symphysiotomy. The following research questions need to be addressed.

- Symphysiotomy versus no symphysiotomy for failure to progress in the second stage of labour when caesarean section is not available, not safe or is declined by the mother.
- 2. Symphysiotomy versus caesarean section in clinical situations in which the relative risks and benefits are considered to be balanced (for example, in women at high risk for abdominal surgery, general anaesthesia or regional analgesia).
- 3. Symphysiotomy versus no symphysiotomy for obstructed birth of the aftercoming head during breech birth.
- 4. (Low priority) Symphysiotomy versus no symphysiotomy for shoulder dystocia unresponsive to conventional management.

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As part of the pre-publication editorial process, this review has been commented on by three peers (an editor and two referees who are external to the editorial team), a member of the Pregnancy and Childbirth Group's international panel of consumers and the Group's Statistical Adviser.



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APPENDICES

Appendix 1. Symphysiotomy technique

Symphysiotomy technique is included in the UK 'Managing Obstetric Emergencies and Trauma' courses (Wykes 2003). The technique is described in Crichton 1963, Quinlan 1995 and in WHO 2001. A brief, slightly modified description follows.

Explain the reason, the procedure and possible complications, and request consent. Ensure that conservative measures to promote birth such as upright posture have been attempted. Symphysiotomy is usually but not exclusively performed when the cervix is fully dilated. The head should be at most 2 cm above the ischial spines or no more than 3/5 above the pelvic inlet, with no over-riding of the head above the symphysis pubis. A vacuum extractor cup may be applied before or after the symphysiotomy is performed. Greater traction is possible with a large metal cup than a flexible cup (see Johanson 2000 review on vacuum extraction).

Provide emotional support and encouragement. Use local infiltration with lignocaine as soon as the decision for symphysiotomy is made or anticipated, to allow time for the analgesic to take effect. Infiltrate the anterior, superior and inferior aspects of the symphysis and the subcutaneous tissues with lignocaine 0.5% solution. Check that no blood can be aspirated before each infiltration. The needle may be left inserted into the joint as a guide for the scalpel incision.

Two assistants support the woman's legs with her thighs and knees flexed with the thighs abducted no more than 90° from each other. Insert a large firm (plastic) catheter to identify the urethra. Apply antiseptic solution to the skin. Confirm adequate analgesia by pinching the skin with forceps. Place an index finger in the vagina and push the catheter and the urethra away from the midline. With the other hand, use a fixed-blade scalpel to make a vertical stab incision over the symphysis. Keeping to the midline, cut down through the fibro-cartilage joining the two pubic bones. Cut the cartilage downwards to the bottom of the symphysis, then rotate the blade and cut upwards to the top of the symphysis. As fixed-blade scalpels are rarely available, the author has used a normal disposable blade scalpel (largest, curved blade available) and incised the joint in one step (without rotating the blade), with sawing action, from the top to the bottom, taking care to leave the most posterior and inferior fibres intact. Traditionally, the finger displacing the urethra is held directly behind the symphysis pubis and the depth of the incision judged by feeling the movement and pressure of the scalpel tip with the internal finger. If the woman is

Van Roosmalen 1987

Van Roosmalen J. Symphysiotomy as an alternative to cesarean section. *International Journal of Gynecology & Obstetrics* 1987;**25**(6):451-8.

Verkuyl 2001

Verkuyl DAA. Symphysiotomies are important option in developing world. *BMJ* 2001;**323**:809.

Verkuyl 2007

Verkuyl DA. Think globally act locally: the case for symphysiotomy. *PLoS Medicine* 2007;**4**(3):e71.

Verkuyl 2008

Verkuyl DA, Ersdal HL, Raassen TJ. Absence of proper training in symphysiotomies resulted in this operation being underused, performed when contraindicated and possibly in a specific kind of urinary fistula. *Acta Obstetricia et Gynecologica Scandinavica* 2008;**87**(12):1380-3.

WHO 2001

WHO, UNFPA, UNICEF, World Bank. Managing complications in pregnancy and childbirth. A guide for midwives and doctors. Geneva: WHO, 2001:53.

Wykes 2003

Wykes CB, Johnston TA, Paterson-Brown S, Johanson RB. Symphysiotomy: a lifesaving procedure. *BJOG: an international journal of obstetrics and gynaecology* 2003;**11**0:219-21.



not known to be HIV-negative, the authors advise that the internal finger displace the urethra even further laterally to be kept well lateral to the symphysis, and that the depth of the incision be controlled by judgement.

Remove the catheter. Perform a mediolateral episiotomy to reduced tension on the para-urethral tissues. Assist the birth of the baby by vacuum extraction, guiding the head away from the symphysis pubis. Descent of the head causes the symphysis to separate 1 cm or 2 cm. After the birth, catheterize the bladder with a self-retaining bladder catheter. Do not suture the stab incision unless there is bleeding. Carefully bring the supported legs together. Apply elastic strapping around the pelvis from one iliac crest to the other to stabilize the symphysis and reduce pain. Loosely bind the knees together with elastic strapping to restrict independent movement of the thighs. Give analgesia. Nurse the woman on her side to aid apposition of the joint surfaces. Encourage ankle exercises in bed. If the woman is considered at high risk for venous thrombosis, give prophylaxis. Leave the catheter in the bladder for a minimum of five days. Encourage mobilisation on crutches, weightbearing on two feet together, as soon as possible (usually within one or two days). Do not allow weightbearing on individual feet until this can be done without discomfort in the pubic region (usually several days).

Appendix 2. Methods of data collection and analysis to be used in future updates

The following methods will be used for data collection and analysis in future updates of this review if more data become available.

Data collection and analysis

Selection of studies

Both review authors will independently assess for inclusion all the potential studies we identify as a result of the search strategy. We will resolve any disagreement through discussion.

Data extraction and management

We will design a form to extract data. For eligible studies, both review authors will extract the data using the agreed form. We will resolve discrepancies through discussion. We will enter data into Review Manager software (RevMan 2008) 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 2009). We will resolve any disagreement by discussion.

(1) 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 methods as:

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

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

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

We will assess the methods as:

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

(3) Blinding (checking for possible performance bias)

We will describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We will judge studies at low risk of bias if they are blinded, or if we judge that the lack of blinding could not have affected the results. We will assess blinding separately for different outcomes or classes of outcomes.

We will assess the methods as:

- adequate, inadequate or unclear for participants;
- adequate, inadequate or unclear for personnel;



• adequate, inadequate or unclear for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

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, 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 can be supplied by the trial authors, we will re-include missing data in the analyses which we undertake. We will assess methods as:

- adequate (less than 10% attrition, balanced between groups and not related to outcomes);
- inadequate;
- unclear

(5) Selective 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:

- adequate (where it is clear that all of the study's pre-specified outcomes, preferably based on a published protocol, and all expected outcomes of interest to the review have been reported);
- inadequate (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.

(6) Other sources of bias

We 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:

- yes;
- no;
- unclear.

(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 *Handbook* (Higgins 2009). With reference to (1) to (6) above, we will assess the likely magnitude and direction of the bias and whether we consider it likely to impact on the findings. We will explore the impact of the level of bias through undertaking '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.

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 (< 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 2008). 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 its 95% confidence interval, and the estimates of T^2 and I^2 .

Subgroup analysis and investigation of heterogeneity

The primary comparisons will be between symphysiotomy and alternative symphysiotomy techniques and other methods of birth (see Types of interventions). We will perform subgroup analyses for the various clinical indications for symphysiotomy (see Types of participants).

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.

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

Sensitivity analysis

We will conduct sensitivity analyses to assess the effect of inclusion of studies with higher risks of bias as outlined above. Sensitivity analyses will include all outcomes.

WHAT'S NEW

Date	Event	Description
23 July 2012	New search has been performed	Search updated.
23 July 2012	New citation required but conclusions have not changed	Review updated. No new trials identified.

HISTORY

Protocol first published: Issue 2, 2005 Review first published: Issue 10, 2010

Date	Event	Description
24 September 2008	Amended	Converted to new review format.



CONTRIBUTIONS OF AUTHORS

GJ Hofmeyr conducted the literature search and contributed to the writing of the review. PM Shweni provided clinical input to the writing of the paper.

DECLARATIONS OF INTEREST

None known.

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.
- (PMS) Eastern Cape Department of Health, South Africa.

External sources

- (GJH) HRP-UNDP/UNFPA/WHO/World Bank Special Programme in Human Reproduction, Geneva, Switzerland.
- (GJH) Rockefeller Foundation Residency, October 2004, USA.

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

Since the protocol was published the Pregnancy and Childbirth Group has updated its methods; we have incorporated these into the review.

We have added 'vesico-vaginal fistula' as a secondary outcome. This was not prespecified in our protocol. We have modified the prespecified maternal secondary outcome 'death' to 'perinatal death'.

INDEX TERMS

Medical Subject Headings (MeSH)

*Symphysiotomy [adverse effects] [methods]; Cephalopelvic Disproportion [*surgery]; Pelvimetry; Pubic Symphysis [surgery]

MeSH check words

Female; Humans; Pregnancy