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Term breech presentation - Caesarean section versus vaginal delivery

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Term breech presentation - Caesarean section versus vaginal delivery [Sätesändläge i fullgången tid - kejsarsnitt eller vaginal förlossning?]

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1. Abstract

Background
In 3% of pregnancies the baby presents as breech at term, i.e. the infant is bottom first instead of head first (cephalic presentation). If external version is unsuccessful, the baby remains in breech presentation when contractions start. Vaginal delivery in breech compared with cephalic presentation increases the risks of complications for the baby, perinatal death as well as the risks for permanent illness and disability. An intended caesarean section (CS) may reduce these risks, but carry potential risks for the mother both during and after surgery as well as in future pregnancies. Optimal delivery method for a baby in term breech presentation is hence still controversial. Today, intended CS delivers 85% of term breech babies in Region Västra Götaland and the question is whether this should be routine for all babies in breech.

Objective
Does the intention to deliver a term infant with breech presentation by CS compared with vaginal delivery, affect perinatal and maternal mortality and morbidity?

Methods
During January 2017 two authors performed systematic searches in PubMed, Embase, the Cochrane Library and Cinahl. These authors selected studies, and independently assessed the abstracts and made a first selection of full-text articles. Inclusion was finally decided in a consensus meeting with all authors. The included studies were critically appraised using checklists. Data were extracted by at least two authors and, when possible, pooled in meta-analyses.

Main results
27 articles (five articles based on one multicentre RCT with 2078 patients, 20 cohort studies (one of them prospective) and two case series) were finally included. The RCT had moderate problems with directness, risk of bias and precision, while the cohort studies mainly suffered from selection bias. All results are presented as the outcome of intended CS compared with intended vaginal delivery.

Child outcomes:
Reduced perinatal mortality for CS was reported in the RCT with marginal statistical significance when stillbirths were excluded; RR 0.27 (95% CI 0.01; 0.97), p=0.06. Fifteen cohort studies demonstrated significantly reduced perinatal mortality after CS.
Conclusion: Intended CS compared with intended vaginal delivery of a term breech infant may reduce the risk of perinatal mortality (GRADE ⊕⊕◯◯).
Reduced child morbidity at short term was reported in the RCT; however only in countries with a low national perinatal mortality. Overall, 14 cohort studies reported different short term morbidity data that could be summarised in four meta-analyses. Only one study reported serious perinatal complications adjusted for confounding factors; OR 0.75 (95% CI 0.35; 1.58).
Conclusion: Intended CS compared with intended vaginal delivery of a term breech infant probably reduces the frequency of Apgar score <7 at 5 min (GRADE ⊕⊕⊕◯), and may reduce the risk of birth traumatic injury and the use of perinatal intensive care (GRADE ⊕⊕◯◯for both).
Child morbidity at long term was reported in the RCT and four cohort studies. Neither of these studies demonstrated any difference in long term child morbidity.
Conclusion: There may be little or no difference in long term child morbidity after intended CS compared with vaginal delivery of a term breech infant. (GRADE ⊕⊕◯◯).

Maternal outcomes:
Maternal mortality was reported in the RCT, three retrospective cohort studies and two case series without any significant differences. Two large case series presented maternal mortality rates after intended CS between 0 and 0.4 ‰.
Conclusion: It is uncertain whether there is any difference in maternal mortality for intended CS compared with intended vaginal delivery of a singleton term breech infant (GRADE ⊕◯◯◯.
Maternal morbidity within the first year was reported in one RCT and three cohort studies.
Conclusion: There may be little or no difference in severe maternal morbidity after intended CS compared with intended vaginal delivery in term breech position (GRADE ⊕⊕◯◯).
Although the negative effect of CS on placental complications in subsequent pregnancies is well known, the documentation specifically on breech presentation is sparse. Thus, conclusions regarding placental complications in subsequent pregnancies after intended CS have to be based on the entire CS literature, regardless of presentation.
Conversion was reported in one RCT and two case series. The rate of conversion from intended vaginal delivery to emergency CS was 44% (95% CI 42%; 46%) (GRADE ⊕⊕⊕◯).

Concluding remarks
Intended CS compared with intended vaginal delivery of term breech babies may reduce the perinatal mortality and short-term child morbidity, whereas the difference in long-term child morbidity may be little or none. There may be little or no difference in maternal mortality and morbidity. Estimated cost change if all term breech babies should be planned for CS is small. The available evidence regarding long term risks for the mother and the infant after intended CS versus vaginal delivery is sparse and it is difficult to advise parents with term breech infants.

2. Svensk sammanfattning – Swedish summary

Bakgrund
I 3 % av alla graviditeter ligger det fullgångna fostret i sätesbjudning, dvs. med sätet istället för huvudet nedåt. Yttre vändning misslyckas i 50 %. Vaginal förlossning vid sätes- jämfört med huvudbjudning ökar risken för komplikationer och död hos barnet under nyföddhetsperioden, liksom risken för permanent sjukdom och handikapp. Planerat kejsarsnitt skulle kunna minska risken men innebär risker för modern under och efter ingreppet och vid framtida graviditeter. Optimal förlossningsmetod för fullgångna foster i sätesbjudning är därför kontroversiell. Idag görs planerat kejsarsnitt i 85 % och frågan är om det skall bli rutin.

Frågeställning
Påverkar planerat kejsarsnitt, jämfört med planerad vaginal förlossning, för fullgångna foster i sätesbjudning den perinatala och maternella dödligheten och sjukligheten?

Metod
Systematisk litteratursökning gjordes i PubMed, Embase, Cochrane Library och ett antal HTA-databaser (januari 2017). Minst två av författarna läste oberoende av varandra artikeltitlar, abstrakt och fulltextartiklar för inklusion av studier och för dataextraktion. Resultaten sammanvägdes i meta-analyser när så bedömdes möjligt.

Resultat
Litteratursökningen resulterade i 27 artiklar (fem artiklar baserade på en multi-nationell RCT med 2078 patienter, 20 kohortstudier (varav en prospektiv) och två fallserier). RCTn hade problem vad gäller överförbarhet, studiekvalitet och precision medan kohortstudierna främst hade problem med selektionsbias. För samtliga utfall redovisas jämförelsen mellan planerat kejsarsnitt och planerad vaginal förlossning av fullgångna foster i sätesbjudning.

Barnutfall:
Minskad perinatal dödlighet redovisades i RCTn men nådde inte statistisk signifikans när två intrauterina dödsfall exkluderades; RR 0,27 (95% CI 0,01; 0,97), p=0.06. Metaanalys av 15 kohortstudier visade signifikant minskad perinatal dödlighet.
Slutsats: Planerat kejsarsnitt jämfört med vaginal förlossning kan minska risken för perinatal död (GRADE ⊕⊕◯◯).
Sjuklighet hos barnet inom 28 dagar reducerades efter kejsarsnitt i RCTn men bara i de länder som hade låg perinatal dödlighet. Totalt redovisades olika korttidsmorbiditetsdata i 14 kohortstudier och för fyra sådana utfall gjordes metaanalyser. Bara i en kohortstudie redovisades allvarlig perinatal morbiditet justerad för störfaktorer; OR 0,75 (95% CI 0,35; 1,58).
Slutsats: Planerat kejsarsnitt jämfört med planerad vaginal förlossning minskar troligen frekvensen av Apgar score <7 vid 5 minuter (GRADE ⊕⊕⊕◯) och kan minska risken för traumatiska fosterskador och behovet av perinatal intensivvård (GRADE ⊕⊕◯◯ för båda utfallen).
Det sågs ingen skillnad i morbiditet hos barnet på lång sikt i RCTn och fyra kohortstudier. Slutsats: Det kan föreligga liten eller ingen skillnad i morbiditet hos barnet långsiktigt efter planerat kejsarsnitt jämfört med planerad vaginal förlossning (GRADE ⊕⊕◯◯).
Maternella utfall:
Maternell död redovisades i en RCT, tre kohortstudier och två fallserier utan signifikanta skillnader i de kontrollerade studierna. I två stora fallserier redovisades en mödradödlighet mellan 0 och 0,4‰ efter planerat kejsarsnitt.

Slutsats: Det är osäkert huruvida det föreligger någon skillnad i mödradödlighet efter planerat kejsarsnitt jämfört med vaginal förlossning (GRADE ⊕◯◯◯).
Maternell morbiditet inom ett år redovisades i en RCT och tre kohortstudier.
Slutsats: Det kan föreligga liten eller ingen skillnad i allvarlig maternell morbiditet efter planerat kejsarsnitt jämfört med planerad vaginal förlossning (GRADE ⊕⊕◯◯.
Placenta komplikationer till följd av tidigare kejsarsnitt är välkända sedan tidigare och bör bedömas i en sökning som inte begränsas till sätesförlossningar.
Akut kejsarsnitt vid planerad vaginal förlossning är vanligt förekommande (44%) och vaginal förlossning vid planerat kejsarsnitt förekommer i ca 10%.

Sammanfattande kommentar
Planerat kejsarsnitt jämfört med planerad vaginal förlossning vid sätesbjudning hos fullgångna foster kan minska perinatal mortalitet och morbiditet hos barnet på kort sikt men på lång sikt kan skillnaden vara liten eller försumbar. Det kan vara liten eller ingen skillnad i maternell sjuklighet och död. Uppskattad kostnadsförändring är liten om alla fullgångna foster i sätesbjudning skulle planeras för kejsarsnitt. Den väsentliga etiska konflikten gäller kort- och långsiktiga risker för barnet respektive mamman. Det vetenskapliga underlaget avseende eventuell skillnad i långsiktig risk för mamma respektive barn efter planerat kejsarsnitt respektive planerad vaginal förlossning är sammanfattningsvis begränsat varför det är svårt att ge säkra råd till föräldrarna.

The above summaries were written by representatives from the HTA-centrum. The HTA report was approved by the Regional board for quality assurance of activity-based HTA. The abstract is a concise summary of the results of the systematic review. The Swedish summary is a brief summary of the systematic review intended for decision makers, and is ended with a concluding summary.

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3. Summary of Findings

Comparison between intended caesarean section (CS) and intended vaginal delivery for term infants in breech position.

Outcomes	Study design Number of studies	Relative effect (95%CI)	Absolute effect (%)	Certainty of evidence GRADE*
Perinatal mortality	1 RCT (n=2,088) 14 cohort (n=348,783)	RR 0.27 (0.0076; 0.974) RR 0.34 (0.23; 0.49)	0.3% vs 1.3 % 0-0.15 vs 0.07-0.39	Low[2] ⊕⊕◯◯
Perinatal morbidity; Apgar score <7 at 5 min	1 RCT (n=2,088) 14 cohort (n=348,783)	RR 0.27 (0.12; 0.58) RR 0.23 (0.16; 0.33)	0.8% vs 3.0% 0.18-2.2 vs 0.09-5.9	Moderate[3] ⊕⊕⊕◯
Perinatal morbidity; NICU admission	4 cohort (n=8,431)	RR 0.82 (0.61; 1.09)	-	
Perinatal morbidity; NICU stay >4 d	1 RCT (n=2,078) 3 cohort (n=37,980)	RR 0.67 (0.19; 2.36) RR 0.69 (0.54; 0.87)	1.4% vs 0.6% 0.95-3.4 vs 4.4	Low[4] ⊕⊕◯◯
Perinatal morbidity; Traumatic birth injury	1 RCT (n=2,000) 7 cohort (n=132,671)	RR 0.43 (0.17, 1.11) RR 0.19 (0.11; 0.32)	0.6% vs 1.4% 0-0.9 vs 0-3.2	Low[4] ⊕⊕◯◯
Child morbidity 3 m; Readmitted to hospital	1 RCT (n=1,457)	RR 0.69 (0.39; 1.20)	2.7% vs 4.0%	Low[4] ⊕⊕◯◯
Child morbidity long term	1 RCT (n=920) 4 cohort (n=2,085)	RR 1.09 (0.52; 2.30) RR not calculated[1]	0.03% vs 0.03%	Low[5] ⊕⊕◯◯
Maternal mortality	1 RCT (n=2,083) 3 cohort (n=33,290)	RR 0.33 (0.01; 8.18) 0.15 (0.01; 2.93)	0/1041 vs 1/1042 0/15,174 vs 3/18,116	Very low[6] ⊕◯◯◯
Maternal morbidity; puerperal infection	2 cohort (n=30,380)	RR 1.03 (0.67; 1.56)	0.9-1.5% vs 0.7-1.7%	Low ⊕⊕◯◯
Maternal morbidity; incontinence, pain at 2yrs	1 RCT (n=917)	-	No difference	Low[7] ⊕⊕◯◯
Maternal morbidity; placental complications next pregnancy	1 cohort (n=33,290)	-	No difference	Very low[8] ⊕◯◯◯
Conversion of delivery mode: From CS From vaginal:	1 RCT (n=2,088) 1RCT+ 2 cohort (n=6,560)		9.6% (95% CI 7.8; 11.6) 44.0% (95% CI 42.0; 46.1)	Low[9] ⊕⊕◯◯ Moderate[10] ⊕⊕⊕◯
Mother's experience	1 RCT (n=917)		No difference	Moderate[11] ⊕⊕⊕◯

NICU= perinatal intensive care unit

Footnotes:
[1] Summary estimate not calculated due to heterogeneous definitions of outcome.
[2] Downgraded two levels due to serious limitations in study design and analysis, and serious imprecision.
[3] Downgraded one level due to serious limitations in study design and uncertain precision.
[4] Downgraded two levels due to serious limitations in study design, serious imprecision and some uncertainty about directness.
[5] Downgraded two levels (RCT) due to serious limitations in study design, serious imprecision and some uncertainty about directness. Downgraded one level (cohort studies) due to serious imprecision and heterogeneous outcomes.
[6] Downgraded three levels due to serious limitations in study design, some uncertainty about directness and very serious imprecision.
[7] Downgraded two levels due to serious limitations in study design, and some uncertainty about directness and precision.
[8] Downgraded one level due to some limitations in study design and very serious imprecision.
[9] Downgraded two levels due to some limitations in study design and very serious indirectness.
[10] Downgraded one level due to some limitations in study design.
[11] Downgraded one level due to some limitations in study design and some uncertainty about directness.

***Certainty of evidence according to GRADE**

High certainty ⊕⊕⊕⊕	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate certainty ⊕⊕⊕◯	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low certainty ⊕⊕◯◯	Confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very low certainty ⊕◯◯◯	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

4. Abbreviations/Acronyms

ASQ	Ages and Stages Questionnaire
DVT	Deep Venous Thrombosis
CS	Caesarean Section
NICU	Neonatal Intensive Care Unit
NNH	Number Needed to Harm
NNT	Number Needed to Treat
PMR	Perinatal Mortality Rate (child died during delivery or the first 28 days)
RCT	Randomised Controlled Trial
SR	Systematic Review
TBT	Term Breech Trial

5. Background

Breech presentation
The majority of infants are born in cephalic presentation, where the head leads the way through the delivery tract. In breech presentation the infant is born bottom first, sometimes with a foot or knee leading. Vaginal delivery in breech compared with cephalic presentation seems to be associated with a greater risk of complications for the baby due to factors such as cord prolapse, aspiration of amniotic fluid or difficulties delivering the after-coming head (Roman et al. 1998). These complications can increase the risk of perinatal death as well as of permanent illness and disability. An intended caesarean section (CS) may reduce these risks for the baby, but carry potential risks for the mother both during and after surgery or in future pregnancies such as uterine rupture, invasive placental growth and hysterectomy (Lawson et al. 2012).

Incidence
According to The Medical Birth Register in Sweden (Socialstyrelsen 2017) approximately 3% of all infants are born in breech presentation. A total of 552 breech deliveries were registered in Region Västra Götaland and 3286 in Sweden 2015. The risk of breech presentation is increased if, e.g., the child or the uterus has some kind of malformation, even though most of the infants and mothers among breech deliveries are totally healthy (Hofmeyr et al. 2015).

Present treatment
In Region Västra Götaland all women carrying a baby in breech presentation are recommended an external version. This is carried out in gestational week 36-37 and is successful in 50% of the cases. In cases where breech presentation persists the mother can choose either an intended CS or, if certain selection criteria are fulfilled, a planned vaginal delivery. Advising the woman is a challenge for the obstetrician since there are no national guidelines or clear recommendations to follow. The Medical Birth Register shows that CS is done in approximately 90% of breech deliveries in Sweden with a regional variation from 76% to 100% in the different counties. In Region Västra Götaland the frequency was 85% during the year of 2015.

Current mode
In a critical review of literature published in 1993 (Cheng et al. 1993) it was suggested that intended vaginal delivery for term infants in breech presentation was associated with three- or four times higher rates of perinatal morbidity and mortality compared with intended caesarean delivery. Some years later the results from the Term Breech Trial (TBT), often referred to as “the Hannah study”, were presented. This was a multicentre randomised controlled trial (RCT) showing a significantly higher risk for perinatal and perinatal death or serious perinatal mortality in the group with intended vaginal delivery compared with the group with intended CS. The main conclusion was to recommend elective CS for term breech foetuses (Hannah et al. 2000). After the publication of the TBT trial, there was a remarkable change in the management of breech deliveries, resulting in many more intended CS in Sweden (Socialstyrelsen 2012). The TBT has been criticised in many ways (Jensen et al. 2015, Mackay et al. 2015) and the preferred way to deliver an infant in breech presentation is still controversial. For example, a French/Belgian prospective observational study (Goffinet et al. 2006) concluded that in centres where intended vaginal deliveries of singleton foetuses in breech presentation at term is a common practice it remains a safe option, provided that strict criteria are met before and during labour.

A recent Cochrane review (Hofmeyr et al. 2015) points out that the short term perinatal benefits of intended CS must be weighed against factors such as an increased risk in future pregnancies for uterine rupture and placental ingrowth, maternal surgical complications, and long term paediatric health problems. Hofmeyr and associates also mention that routine intended CS was widespread in developed countries, without clear evidence that such a policy was preferable.

6. Health Technology at issue: Elective caesarean section for all term breech presentations

In about 3% of all pregnancies the baby presents as breech at term. In Sweden most obstetric departments offer external version, hence the incidence of breech presentation is lower when contractions start. Optimal mode of delivery of these babies regarding the safety of both the mother and the baby has been an issue among obstetricians for a long time, ever since the possibility of a safe caesarean section increased. Uncertainty about breech management has led to variations in practice at the different delivery wards in Sweden. These variations have warranted us to identify current scientific knowledge in the area. In summary, we aimed to study the best way to deliver a baby in term breech presentation with regard to the short and long term health of the mother and baby as well the economical aspect.

7. Objective

To evaluate if the intention to deliver a term infant with breech presentation by CS compared with intended vaginal delivery, affects perinatal and maternal mortality and morbidity and long term outcomes for mother and child.

PICO: P= Patients, I= Intervention, C= Comparison, O=Outcome

P Pregnant women with a child in breech presentation, from gestational week 34+0.
I Intention to deliver by caesarean section
C Intention to deliver vaginally
O
Critical (for decision making):
-Perinatal mortality
-Short term perinatal outcome (perinatal morbidity):
- stay at neonatal care unit
- hypoxic ischemic encephalopathy (HIE)
- intracranial bleeding
- asphyxia (Apgar score <7 at 5 minutes
- pH ≤ 7.05
- base excess (BE) ≤ -12
- traumatic birth injury

-Long term child outcome: neurodevelopmental or physical problems
-Maternal mortality
-Short term maternal outcome:
- Infection
- bleeding
- thrombosis
- delivery tract trauma

-Long term maternal outcome:
pelvic floor dysfunction
placenta praevia/accrete in subsequent pregnancies
uterine rupture in subsequent pregnancies

(All suggested morbidity outcomes are not critical, particularly surrogate outcomes are important, rather than critical, but they will be reported under the heading “Critical outcomes- morbidity”.

Important (but not critical for decision making):
-Conversion of delivery mode
-The mother’s experience of delivery

8. Methods

Systematic literature search (Appendix 1)
During January 2017 two authors (TS, IS) performed systematic searches in PubMed, Embase, the Cochrane Library and Cinahl. The Swedish Agency for Health Technology Assessment and Assessment of Social Services (SBU) and Kunnskapssenteret and reference lists of relevant articles were also scrutinised for additional references. Search strategies, eligibility criteria and a graphic presentation of the selection process are presented in Appendix 1. These authors conducted the literature searches, selected studies, and independently of one another assessed the obtained abstracts and made a first selection of full-text articles for inclusion or exclusion. Any disagreements were resolved in consensus. The remaining articles were sent to all the participants of the project group. At least two authors read each article independently of one another and it was finally decided in a consensus meeting with all authors which articles should be included in the assessment.

Critical appraisal and certainty of evidence
The included studies and their design and patient characteristics are presented in Appendix 2. The excluded studies and the reasons for exclusion are presented in Appendix 3. The included studies, except for case series, have been critically appraised using a checklist for assessment of randomised controlled trials, modified from the SBU by HTA-centrum and a checklist for assessment of cohort studies, also modified from SBU by HTA-centrum. The results and the assessed quality of each article have been summarised per outcome in Appendix 4. Data were extracted by at least two authors per outcome. When possible, data were pooled in meta-analyses using a random effects model in RevMan 5.2 and presented as forest plots. Continuous data presented with median and IQR, was transformed to mean and SD, assuming normal distribution.
A summary result per outcome and the associated certainty of evidence are presented in a Summary-of-findings table (page 8). The certainty of evidence was defined according to the GRADE system (Atkins et al, 2004; GRADE Working group).

Ongoing research
Searches in Clinicaltrials.gov (2017-04-26) and WHO International Clinical Trials Registry Platform (2017-04-27) using the search term breech identified 34 and 41 trials, respectively. After removal of duplicates, a total of 53 trials were identified. None of these trials was relevant for our question.

9. Results

Systematic literature search (Appendix 1)

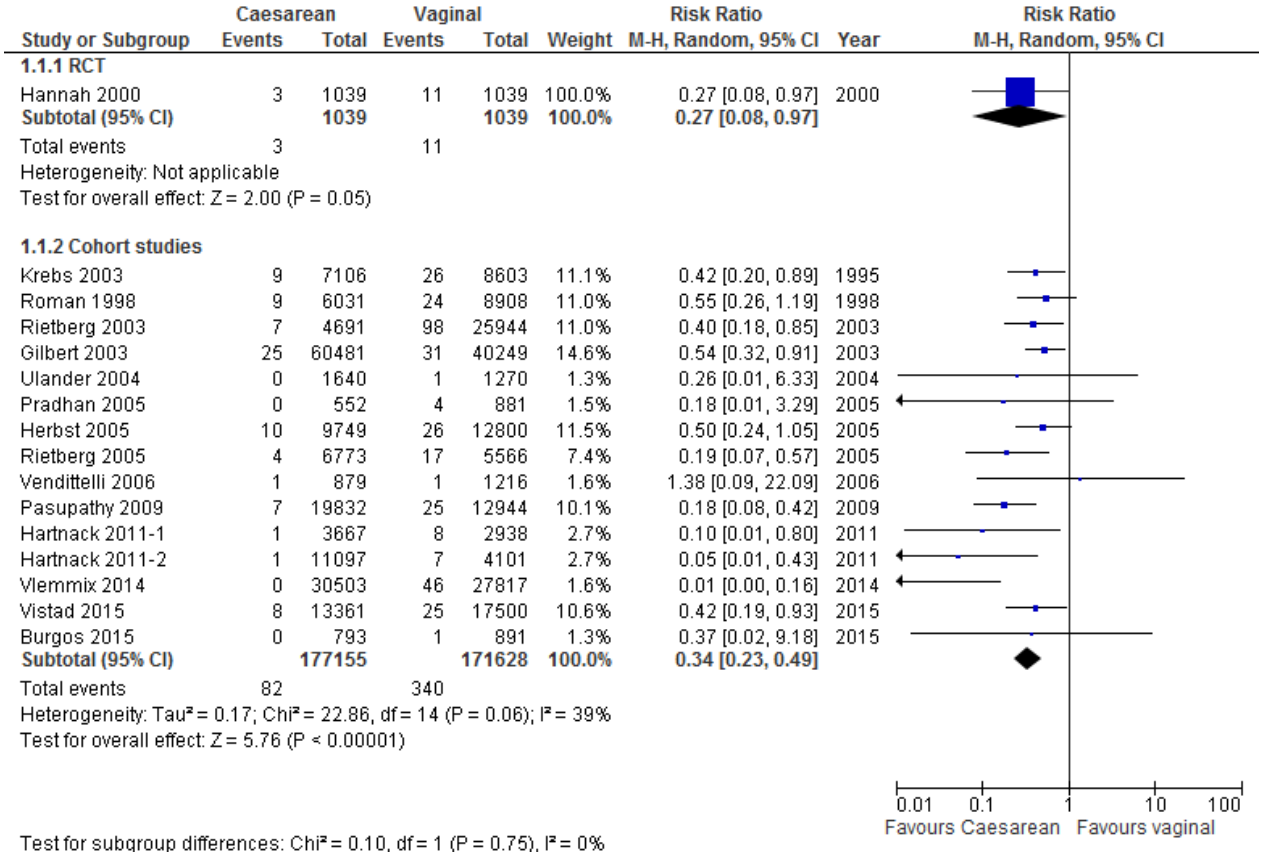
The literature search identified 1792 articles after removal of duplicates. After reading the abstracts 1684 articles were excluded. Another 44 articles were excluded by two authors after reading the articles in full text. The remaining 64 articles were sent to all participants of the project group, and 27 articles (five publications from one RCT, 20 cohort studies and two case series) were finally included in the assessment (Appendix 2). In addition, one health economy study was commented upon.

Outcomes critical for decision-making

Perinatal mortality (Appendix 4.1)

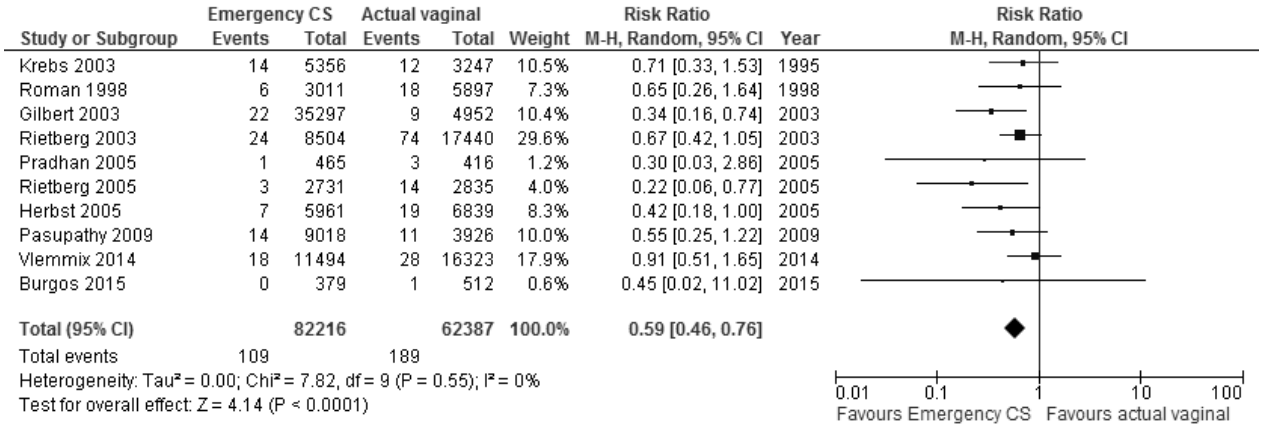
Perinatal mortality was reported in one RCT and 17 cohort studies (one of them prospective), comparing the two intended delivery routes. The RCT had moderate problems with directness, risk of bias and precision, while the cohort studies mainly suffered from selection bias. The RCT with 2078 patients demonstrated a reduced perinatal mortality with marginal statistical significance when stillbirths were excluded; RR 0.27 (95% CI 0.008; 0.97), p=0.06. Fourteen cohort studies (n= 348,783) reported crude unadjusted data that could be summarised in a meta-analysis; RR 0.34 (95% CI 0.23; 0.49), (Fig.1).

Fig.1. Metaanalysis of studies comparing intended caesarean section with intended vaginal delivery. Outcome: Perinatal mortality



An analysis within the intended vaginal delivery group, comparing those who underwent emergency CS during labour with those who completed a vaginal delivery was undertaken.
Based on crude unadjusted data from eleven cohort studies including 144,603 patients, a reduced risk of perinatal mortality was demonstrated after emergency CS compared with vaginal delivery; RR 0.59 (95% CI 0.46; 0.76) (Fig. 2).

Fig. 2. Metaanalysis of studies comparing emergency caesarean section with completed vaginal delivery among those with the intention to deliver vaginally
Outcome: Perinatal mortality

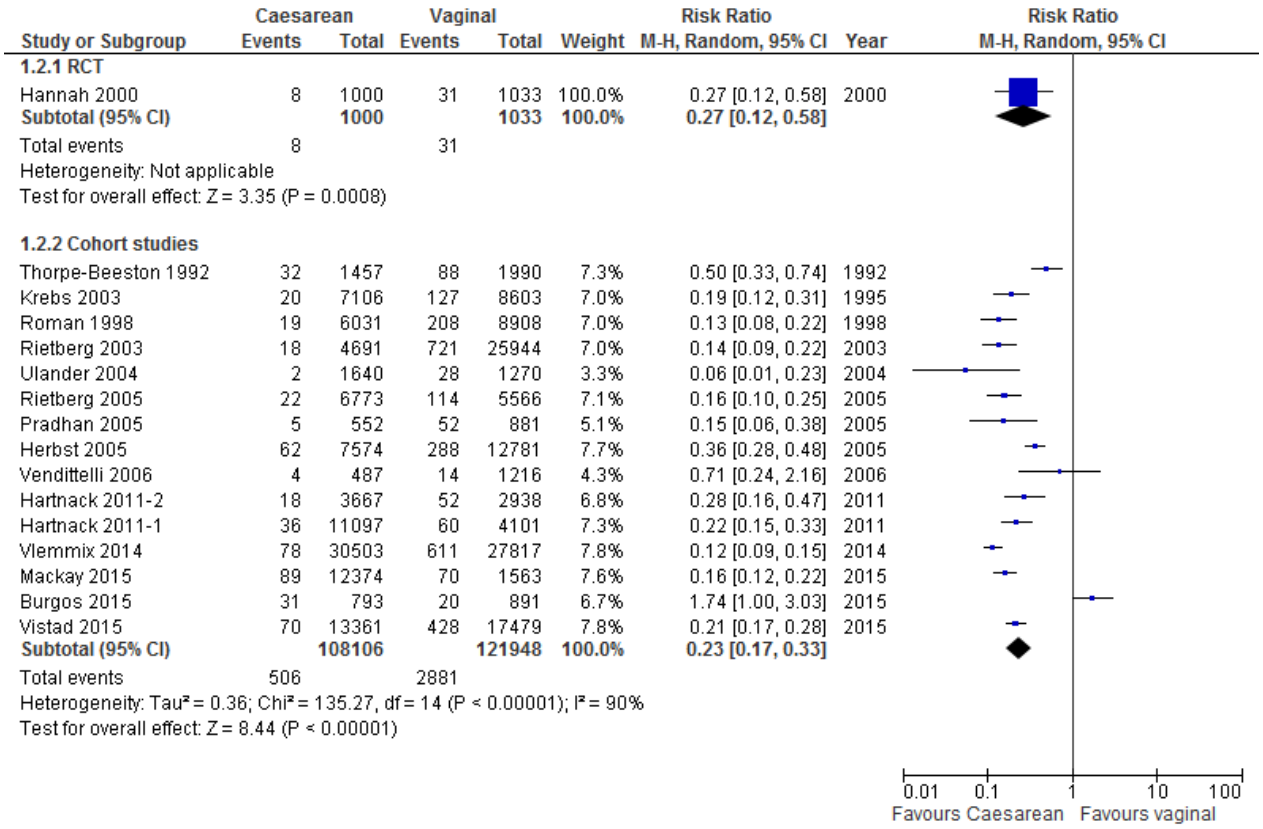


Conclusion: Intended CS compared with intended vaginal delivery of a singleton term infant with breech presentation may reduce the risk of perinatal mortality.
Low certainty of evidence (GRADE ⊕⊕◯◯).

Child morbidity, short term (Appendix 4.2)
Child morbidity, short term was reported in one RCT and 17 cohort studies (one prospective), comparing the two intended delivery routes; CS versus vaginal delivery. The RCT had moderate problems with directness, risk of bias and precision, while the cohort studies mainly suffered from serious inconsistency. The RCT demonstrated a reduced short-term child morbidity; RR 0.36 (95% CI 0.19; 0.65), however only in countries with a low national perinatal mortality (PMR).
Only one study (Vendittelli et al. 2006) reported adjusted data for serious perinatal complications; OR 0.75 (95% CI 0.35; 1.58).

Apgar score <7 at 5 minutes
One RCT and 14 cohort studies reported Apgar score <7 at 5 minutes as a surrogate measure for child morbidity. All but two studies demonstrated a significantly reduced frequency of Apgar score <7 at 5 minutes after intended CS compared with intended vaginal delivery (Fig. 3). The meta-analysis of the cohort studies displayed a very high heterogeneity (I^2 90%), probably explained by the differences in the study populations. However, the RR 0.23 was similar to the RR 0.27 in the RCT (Fig. 3).

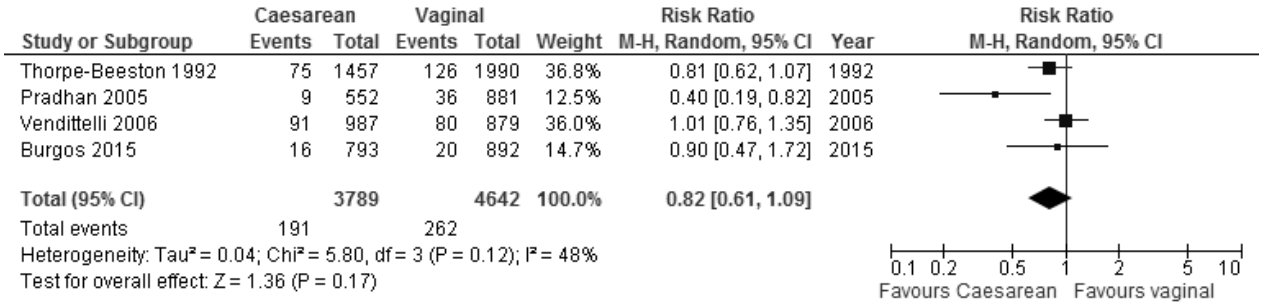
Fig.3. Metaanalysis of studies comparing intended caesarean section with intended vaginal delivery
Outcome: Apgar score <7 at 5 minutes



Conclusion: Intended CS compared with intended vaginal delivery in term breech deliveries probably reduces the frequency of Apgar score<7 at 5 minutes.
Moderate certainty of evidence (GRADE⊕⊕⊕◯).

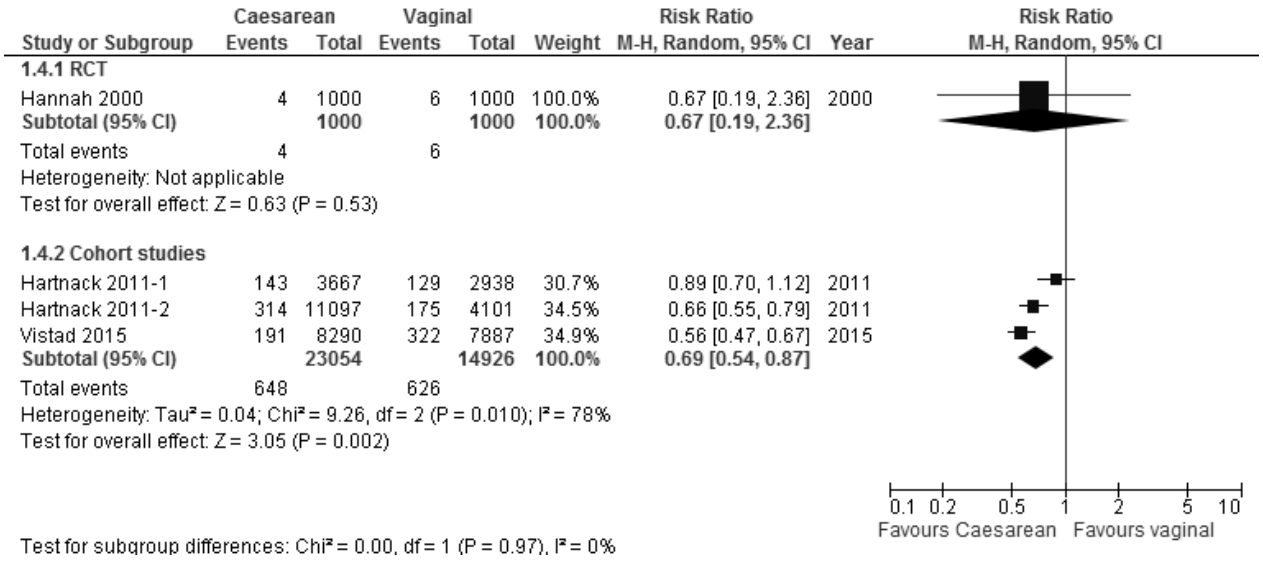
<u>Admission and stay at neonatal intensive care unit (NICU)</u>
Four cohort studies reported admission to NICU. The pooled estimate did not demonstrate any statistical difference between intended delivery modes; RR 0.82 (95% CI 0.61; 1.09), (Fig. 4).

Fig. 4. Metaanalysis of studies comparing intended caesarean section with intended vaginal delivery.
Outcome: NICU admission



One RCT and four cohort studies reported NICU stay longer than four days as a measure of child morbidity. This outcome is likely to correlate better with long-term child morbidity than shorter stays at NICU. The only RCT reported very few events, and the difference was not of any statistical significance (0.4% vs 0.6%).
Based on crude unadjusted data including 37,980 patients, a reduced risk of a NICU stay > 4 days was shown after CS compared with vaginal delivery; RR 0.69 (95% CI 0.54; 0.87) (Fig. 5).

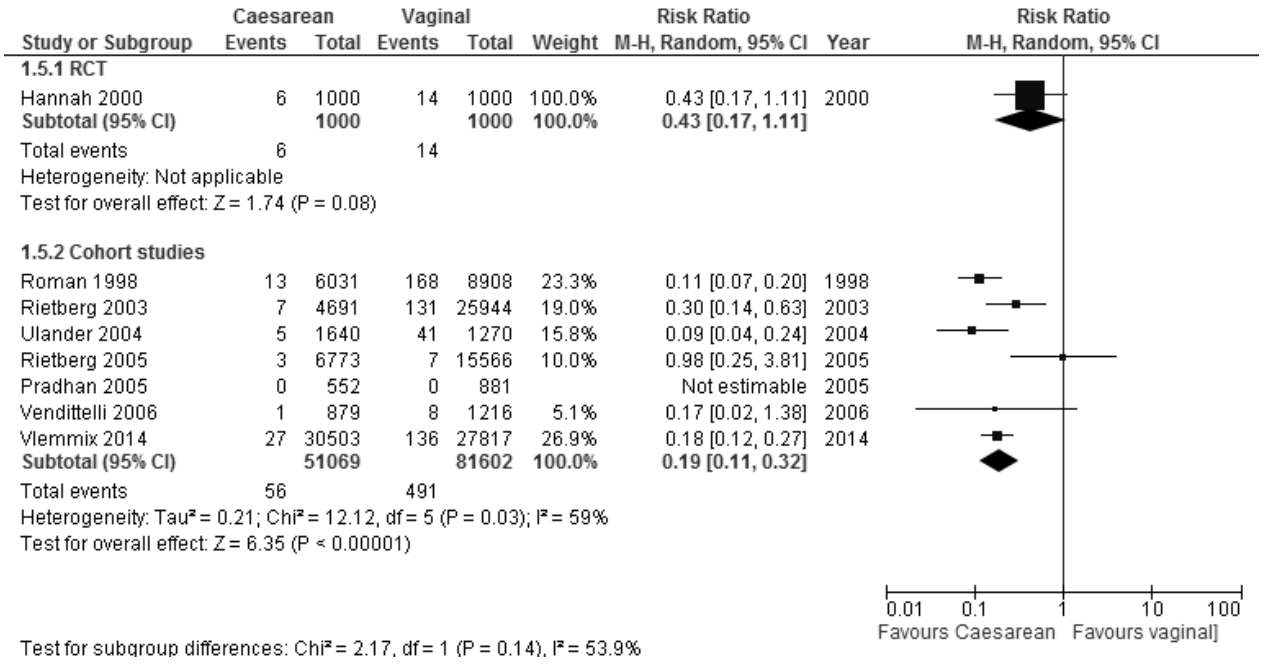
Fig.5. Metaanalysis of studies comparing intended caesarean section with intended vaginal delivery
Outcome: NICU stay > 4 days



Conclusion: There may be a reduced frequency of NICU stay > 4 days for infants born after intended CS compared with intended vaginal delivery in term breech deliveries, however not significantly decreased in the RCT.
Low certainty of evidence (GRADE ⊕⊕◯◯).

Traumatic birth injury
One RCT and ten cohort studies reported traumatic birth injury (including brachial plexus injury). The RCT reported a slight difference in traumatic birth injury between intended CS (0.6%) and intended vaginal delivery (1.4%). Based on crude unadjusted data from seven cohort studies including 132,671 patients, a reduced risk of birth traumatic injury (including brachial plexus injury) was demonstrated after intended CS compared with intended vaginal delivery; RR 0.19 (95% CI 0.11; 0.32), (Fig. 6).

Fig. 6. Metaanalysis of studies comparing intended caesarean section with intended vaginal delivery. Outcome: Traumatic birth injury



Conclusion: Intended CS compared with intended vaginal delivery in term breech deliveries may decrease the frequency of birth traumatic injury.
Low certainty of evidence (GRADE ⊕⊕◯◯).

Child morbidity, 28 days-2 years (Appendix 4.3)

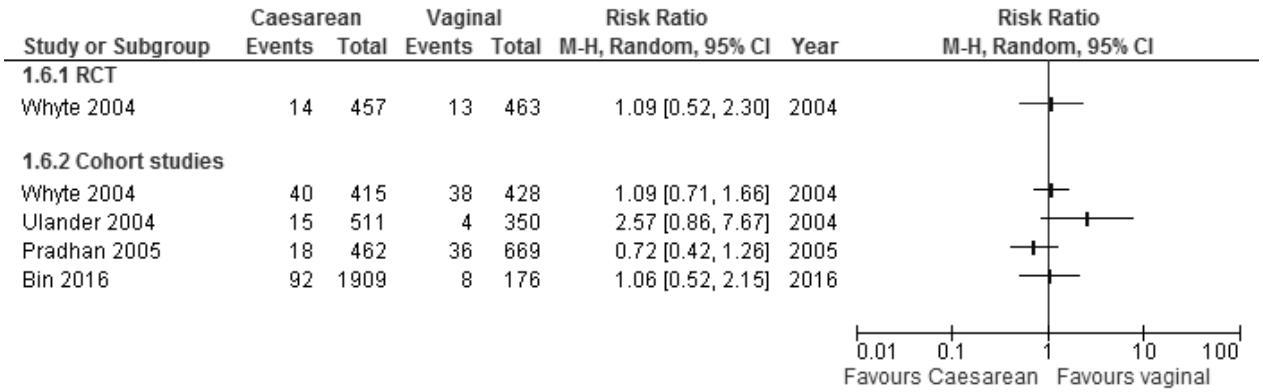
Child morbidity within 28 days to two years was reported in one RCT including 1,940 patients comparing the two intended delivery routes. At three months follow-up, no difference in child morbidity was demonstrated.

Conclusion: There may be little or no difference in child morbidity after three months for intended CS compared with intended vaginal delivery of a singleton term infant with breech presentation.
Low certainty of evidence (GRADE ⊕⊕◯◯).

Child morbidity long term (Appendix 4.4)

Long term child morbidity was reported in one RCT (Whyte 2004) and four cohort studies with a maximum follow up of 18 years.
The RCT with 920 patients demonstrated no significant difference in death or neurodevelopmental delay at two years, nor did the cohort studies show any difference in special needs/ intellectual disability (Fig. 7). No summary estimate was calculated, due to heterogeneous definitions of the outcome.

Fig.7. Forest plot of studies comparing long term child morbidity after intended caesarean section compared with intended vaginal delivery for term breech presentation.

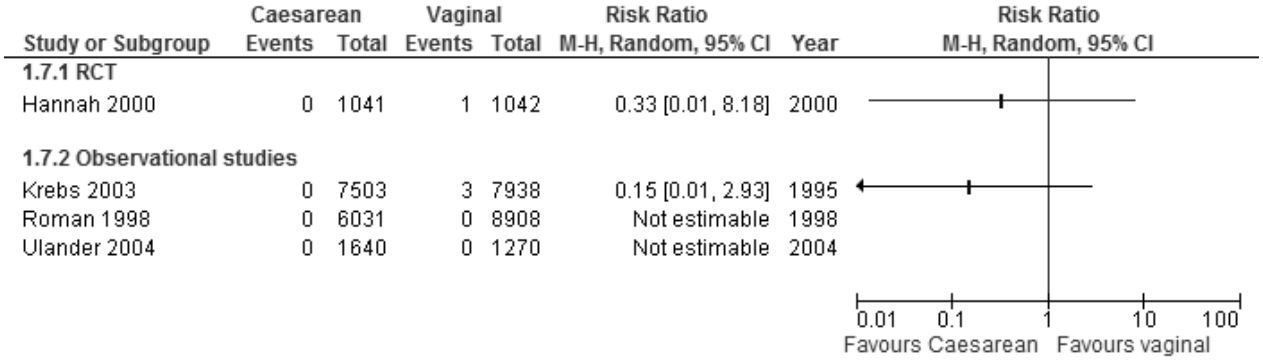


Conclusion: There may be little or no difference in long term child morbidity after intended CS versus intended vaginal delivery for term breech presentation.
Low certainty of evidence (GRADE ⊕⊕◯◯).

Maternal mortality (Appendix 4.5)

Maternal mortality was reported in one RCT, three retrospective cohort studies and two case series. The only RCT had serious problems with directness and study limitations and very serious imprecision, while the cohort studies mainly suffered from serious imprecision. No significant difference was shown in the RCT or in the cohort studies (Fig. 8). One large case series (Liu et al. 2007) had no reported case of maternal mortality in the group of 46,766 intended CS of a singleton term infant with breech presentation. In the group of 2,292,420 intended vaginal deliveries (both breech and cephalic presentation), there were 41 (0.02‰) cases of maternal mortality. In the second case series (Schutte et al. 2007) of four maternal deaths, the maternal mortality was reported to be 0.4‰ in the group of intended CS and 0.1‰ in the group of intended vaginal delivery resulting in CS.

Fig. 8. Forest plot of studies comparing intended caesarean section with intended vaginal delivery.
Outcome: Maternal mortality

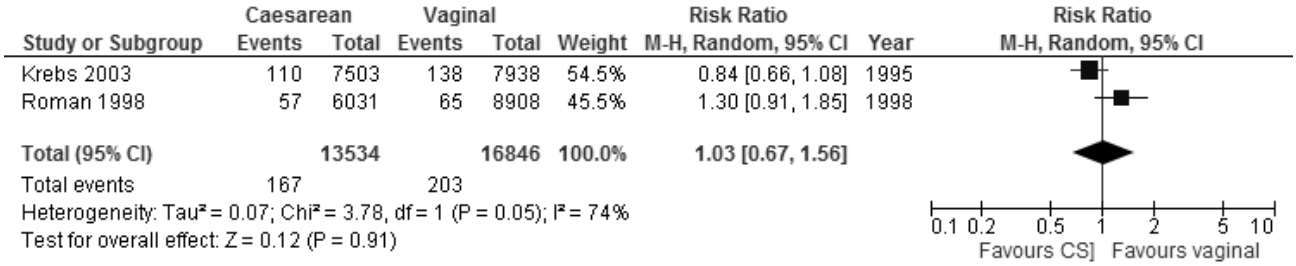


Conclusion: It is uncertain whether there is any difference in maternal mortality for intended CS compared with intended vaginal delivery of a singleton term infant with breech presentation.
Very low certainty of evidence (GRADE ⊕◯◯◯).

Maternal morbidity, first year (Appendix 4.6)

Maternal morbidity within the first year was reported in one RCT and three cohort studies. Serious maternal morbidity within 28 days was observed in 3.9% and 3.1% (n.s.) in the intended CS and vaginal delivery groups respectively in the TBT. Three months follow up in the TBT showed no differences for many outcomes. There was a significant difference for having experienced urinary incontinence (4.5% and 7.3%, p= 0.02), for intended CS and vaginal delivery respectively and also for having experienced incontinence of flatus. In a large Swedish cohort study total complication rates were 1.7% and 2.2% in the intended CS and vaginal delivery groups respectively. Two large cohort studies showed no difference in puerperal infections (Fig. 9).

Fig. 9. Metaanalysis of studies comparing intended caesarean section with intended vaginal delivery. Outcome: Puerperal infection



Conclusion: There may be little or no difference in serious maternal morbidity after intended CS compared with intended vaginal delivery in term breech position.
Low certainty of evidence (GRADE ⊕⊕◯◯).

Maternal morbidity, long term (Appendix 4.7)

Maternal morbidity, long term was reported in one RCT and one retrospective cohort study. The RCT had a follow-up period of two years and demonstrated no significant differences regarding different types of incontinence and pain.

Conclusion: There may be little or no difference in maternal morbidity (incontinence and pain) in long term follow-up after intended CS compared with intended vaginal delivery in term breech position.
Low certainty of evidence (GRADE ⊕⊕◯◯).

The cohort study looked for a difference in second and third pregnancy with regard to uterine rupture and placenta praevia. There were very few events and no significant difference was observed. This rare outcome is better studied in a search including CSs among all presentations and not only breeches, since the results will be applicable also to the breech CSs. No conclusion can be drawn from the present search.

Conversion of delivery mode (Appendix 4.8)

Conversion of delivery mode was reported in one RCT and two retrospective cohort studies. The RCT reported conversion of intended CS to vaginal delivery in 9.6% (95% CI 7.8%; 11.6%) and intended vaginal deliveries resulted in an emergency CS in 43.3% (95% CI 40.3%; 46.3%). The two cohort studies reported 42.5% and 46% conversion rate to emergency CS among intended vaginal deliveries. The point estimate including all three studies was 44.0% (95% CI 42.0%; 46.1%).

Conclusion: The conversion rate from intended vaginal delivery to emergency CS was high (44%).
Moderate certainty of evidence (GRADE ⊕⊕⊕◯).

The conversion rate from intended CS to vaginal delivery was limited (10%).
Low certainty of evidence (GRADE ⊕⊕◯◯).

Mother's experience of delivery (Appendix 4.9)
The mother's experiences of delivery were reported in two publications from one RCT. No differences were reported between intended CS and intended vaginal delivery at either of the two time periods; three months and two years.

Conclusion: There is probably little or no difference in mother's experiences of the delivery both in the short and long term, after intended CS compared with intended vaginal delivery in breech position at term.
Moderate certainty of evidence (GRADE ⊕⊕⊕◯).

10. Ethical issues

In this report we aimed to evaluate whether term breech babies should be delivered by elective CS or planned vaginal delivery. Today in Sweden, most babies in breech position are delivered by CS. If practice would be changed to only CS it would imply a marginal change in costs and use of operation rooms. Therefore no displacement effects on other groups in the health care system are expected in this case. The main ethical conflict exists between the mother and her unborn child. How do you compare risks for the mother due to an operative delivery, both short-term as well as affecting subsequent pregnancies and future children, with the risks that affect the child born vaginally in breech? One of the medical-ethical principles is autonomy. After proper information it is important to let the woman take part in the decision how to deliver her baby. Another medical-ethical principle is fairness. We aim to treat all patients according to this principle but today women with a term breech pregnancy are given various advices depending on by whom they are informed and the opinions of that particular doctor. We need more standardised written information to guarantee that all women in this situation receive the same information and have equal opportunities to make an informed choice. Still, there are other important factors, particularly the obstetrician's competence and experience that inevitably will have a great impact on the management of breech deliveries.

11. Organisational aspects

Time frame for the putative introduction of the new health technology
The increased number of CS would be about 30 per year at Sahlgrenska University Hospital. Currently we perform about 1800 caesarean sections annually and an increase of 30 more CS per year will be managed within the existing organisation. Thus, we can start delivering all term breech presentations with CS at once since increased economic resources, additional training of staff or expansion of surgical sites are not needed.

Present use of the technology in other hospitals in Region Västra Götaland
Caesarean section is a well-established delivery technique and is used in every delivery ward in the developed world.

Consequences of the new health technology for personnel
None.

Consequences for other clinics or supporting functions at the hospital or in the Region Västra Götaland
None.

12. Economic aspects

Present costs of currently used strategy

During 2016, 301 babies were in breech presentation at birth at the Sahlgrenska University hospital, out of which 275 babies were delivered by CS and 26 vaginally. The total health care cost for the breech deliveries were 17.5 million SEK. Included in this total health care cost were the costs for the whole episode of care during the deliveries, such as costs for health care personnel, operating room, labour and delivery ward, oxytocin, prostaglandins, analgesia, anaesthesia, postpartum ward. Stay at the neonatal care unit and medicines are not included. The average cost for CS was 60,419 SEK (range; 8,992 SEK to 2,670,995 SEK) and the average cost for vaginal breech deliveries was 24,829 SEK (range; 8,992 SEK to 57,000 SEK). The mean difference in costs between CS and vaginal breech deliveries was 35,590 SEK (95% CI; 16,119 SEK to 55,061 SEK).

Expected costs of the new strategy

With the currently used strategy, 9% of the babies in breech presentation were delivered with vaginal birth. If instead all 301 babies in breech presentation were delivered with caesarean section the total cost would be 18.2 million SEK. However, some of the babies would still need to be delivered vaginally, estimated to 2% (6 of 301 babies). With this scenario, the total cost would be 18 million SEK.

Total change of cost

If all 301 babies in breech presentation would be delivered with caesarean section the total cost of the deliveries would increase with 670,000 SEK. If instead 2% of the babies in breech presentation would be delivered vaginally and 98% of the babies delivered by CS, the total cost would increase with 460,000 SEK. There is a possibility that the need for neonatal health care will decrease if all term breech babies are delivered by CS, and a possible reduction of cost at the neonatal care unit.

Possibility to adopt and use the new technology within the present budget

It would be possible to fit the increased cost in the present budget.

Available economic evaluations or cost advantages/disadvantages

Palencia and co-workers estimated the cost of intended CS and intended vaginal delivery for babies in breech presentation from a multi-centre study, applied into the Canadian setting with a third-party-payer (Ministry of Health) perspective. The study showed that the estimated mean cost of intended CS were significantly lower in comparison with intended vaginal delivery, $7,165 compared to $8,042 with a mean difference -$877 (95% credible interval -$1,286 to -$473). This study presents an opposite result compared to the economic analysis in this report. It is however in general problematic to compare health care costs between different countries due to different health care systems and settings with different unit costs. The major difference between the study by Palencia et al. and the economic analysis in this study is that Palencia et al. included the cost of neonatal care in their study while in this report it was not possible to include the specific neonatal care unit cost for the babies in breech presentation. We know that 25% of breech babies born vaginally at SU are admitted to the neonatal care unit at SU, to be compared with 3% in babies born vaginally in an obstetric low risk group (Robson 1= cephalic position after a healthy pregnancy from a healthy nulliparous mother with spontaneously started contractions) and also in comparison with 10% suggested as a standard health care need for the neonates in a Swedish delivery ward. The mean stay for all breech babies (regardless of gestational length) is 17.5 days in 2017 at SU.

13. Discussion

In this HTA report we analysed if mothers with term breech babies should be advised to deliver by CS or vaginally. Five of the 30 included articles are based on one RCT named the Term Breech Trial (TBT) published in 2000. Most of the included articles in the present HTA are cohort studies (n=20), mainly retrospective. The cohort studies are from different settings according to health care system and perinatal morality rate. We also included one cost analysis based on the TBT and two case reports.

We observed that intended CS as mode of delivery of a singleton term infant in breech presentation may reduce the risk of perinatal mortality compared with intended vaginal delivery. Intended CS may reduce the short-term child morbidity, whereas there may be little or no difference in child morbidity after three months or at long-term follow-up. Studies considering long-term child morbidity were underpowered and hence no firm conclusion could be drawn. The long term consequences for a child delivered by CS is hence not yet completely known; hopefully ongoing research will give us more knowledge in this field.

Data on perinatal mortality from cohort studies were used to calculate the numbers needed to treat (NNT) to avoid one outcome. NNTs for perinatal death was 406, 411, 400 in Denmark and Sweden (Krebs et al. 2003, Hartnack et al. 2011, Herbst et al. 2005), and 338 in the Netherlands (Vlemmix et al. 2014), i.e. approximately 400 CSs needed to be done to save one baby from dying. NNTs to avoid the outcome Apgar score less than 7 after 5 minutes were 84, 76 and 70 (Krebs et al. 2003, Hartnack et al. 2011, Herbst et al. 2005).

There may be little or no difference in maternal mortality when the different delivery modes were compared. For maternal morbidity, CS compared with vaginal delivery may reduce urinary incontinence.

One of the reasons why we generally try to minimise the use of CS is the risk of uterine rupture or invasive placental growth in a subsequent pregnancy. Only one study in this HTA-report, a large population-based retrospective cohort study, reported uterine rupture as an outcome (Krebs et al. 2003). Due to a rare occurrence with very few events, no inference could be made. If the study data were used to calculate the numbers needed to harm (NNH), i.e. numbers of performed CSs to cause a placental complication in a subsequent pregnancy, NNH for placenta praevia was 6173 and for uterine rupture 2415. On the contrary, deep venous thrombosis (DVT) was more common in the intended vaginal delivery group, also including deliveries that were converted to CS; NNH 12,173.
In a recent cohort study from Sweden, 7683 women who had previously delivered by CS and attempted vaginal birth in their subsequent deliveries were analysed (Hesselman et al. 2015). Uterine rupture during labour occurred in 1.3% of these women. Placenta praevia and placenta accreta were other long term complications strongly associated with prior CS and increased risks of haemorrhage, peripartum hysterectomy and maternal mortality. In a large prospective observational cohort of over 30,000 planned CSs, the rate of placenta accreta in a subsequent pregnancy was 0.24% after one prior CS and 6.74% after six prior CSs. The same study found placenta praevia in 6.42% of women with one prior CS compared with 0.23% in women without prior CS (Silver et al. 2006). This is a reminder that we need to take future pregnancies into account when considering a CS.

Four previous systematic reviews (SR) were identified; two of them were relevant to our work. A Cochrane review included three RCTs with 2396 women and showed reduced perinatal mortality and severe perinatal morbidity favouring intended CS in settings with low perinatal mortality rate (Hofmeyr et al. 2015). Intended CS modestly increased short-term maternal morbidity. At two years the maternal outcomes were similar in the two groups.

The authors concluded that children born with CS had more health care problems at two years of age but no difference in mortality or neurodevelopmental delay. The TBT trial results totally dominate the mentioned SR; the other included studies were small and old. The second SR included 27 articles with a total of 258,953 women (Berhan et al. 2016. They found the relative risk of perinatal mortality and morbidity two to five times higher in the intended vaginal compared with the intended CS group. Shortcomings in this latter SR include a lack of multivariable analyses and no quality assessment of the included studies.

The Term Breech Trial led to increased numbers of intended CS in term breech presentation. Today, CS delivers a majority of term breech babies. As previously discussed by other authors, we found serious limitations in the TBT trial publications. First of all, only 2088 women from 121 centres in 26 countries were included during the study implying that each centre included only an average of five term breech deliveries annually. This suggests that it is a highly selected group although this is poorly discussed in the TBT publications. Secondly, the primary outcome is a composite of mortality and serious morbidity for the child, ranging from death to minor injuries. In the article Hannah et al, 2000, the result regarding the primary outcome is reported as statistically significant but the analysis was conducted using a one-sided test. A two-sided test would result in p=0.06. Furthermore, two stillbirths were included in the group with intended vaginal delivery. When these are excluded, the difference in the composite outcome was no longer significant. It seems like there were more complications in the intended vaginal delivery group than expected and therefore we suspect a selection bias where high risk deliveries were more likely to be included in the TBT than low risk deliveries.

Many of the included studies in this HTA-report do not report type of breech presentation, a factor that can affect outcome. We also know that the medical guidelines in the different studies sometimes differ from ours, e.g. induction and use of oxytocin. Such details can affect the applicability of the results to our setting. If we change our policy and plan CS for all breech babies the knowledge how to deliver them vaginally may be lost. However, a few women with undiagnosed breech position will come to the hospital in the final stage of delivery when it is too late to make an emergency CS. Also, in deliveries of twins, the second twin may present in breech position. To be able to deliver these babies in a safe way we need to keep the competence of vaginal delivery in breech position by practising simulated situations like we do with other rare but serious conditions.

14. Future perspective

Scientific knowledge gaps

Since breech presentation is rare and severe perinatal morbidity and mortality are even more rare events it is difficult to perform randomised studies. Hence the current evidence is limited, although the literature quite coherently points towards intended CS having positive effects on perinatal mortality and short-term morbidity. Furthermore, there are knowledge gaps concerning long-term outcome for the children as well as maternal mortality and morbidity.

Ongoing research

No ongoing studies applicable to our PICO were identified in Clinicaltrials.gov or WHO ICTRP. The ongoing research on breech position is mainly concerning different methods of external version.

15. Participants in the project

The question was nominated by

Corinne Pedroletti, head of Department of obstetrics, Sahlgrenska Universitetssjukhuset (SU)

Participating health care professionals

Julia Wängberg Nordborg, MD, Department of obstetrics and gynaecology, SU
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Ylva Carlsson, MD, PhD, Department of obstetrics and gynaecology, SU
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Participants from the HTA-centrum

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Ida Stadig, librarian, Medical Library, SU, Gothenburg
Therese Svanberg, HTA librarian, HTA-centrum, Region Västra Götaland
Josefine Persson, PhD, Health economist, HTA-centrum, Region Västra Götaland

External reviewers

Margareta Hellgren, MD, professor emerita, Department of obstetrics and gynecology, SU
Maria Skogby, RN, PhD, Department of Neonatology, SU

Declaration of conflicts of interest

None of the authors has any conflict of interest to declare.

Project time

HTA was accomplished during the period of 2017-01-10 – 2017-10-25.
Literature searches were made in January 2017.

Appendix 1: Search strategy, study selection and references

PICO

Project: Mode of delivery for breech presentation

Objective: To evaluate if the intention to deliver a term infant with breech presentation by CS compared with intended vaginal delivery, affects perinatal and maternal mortality and morbidity and long term outcomes for mother and child.

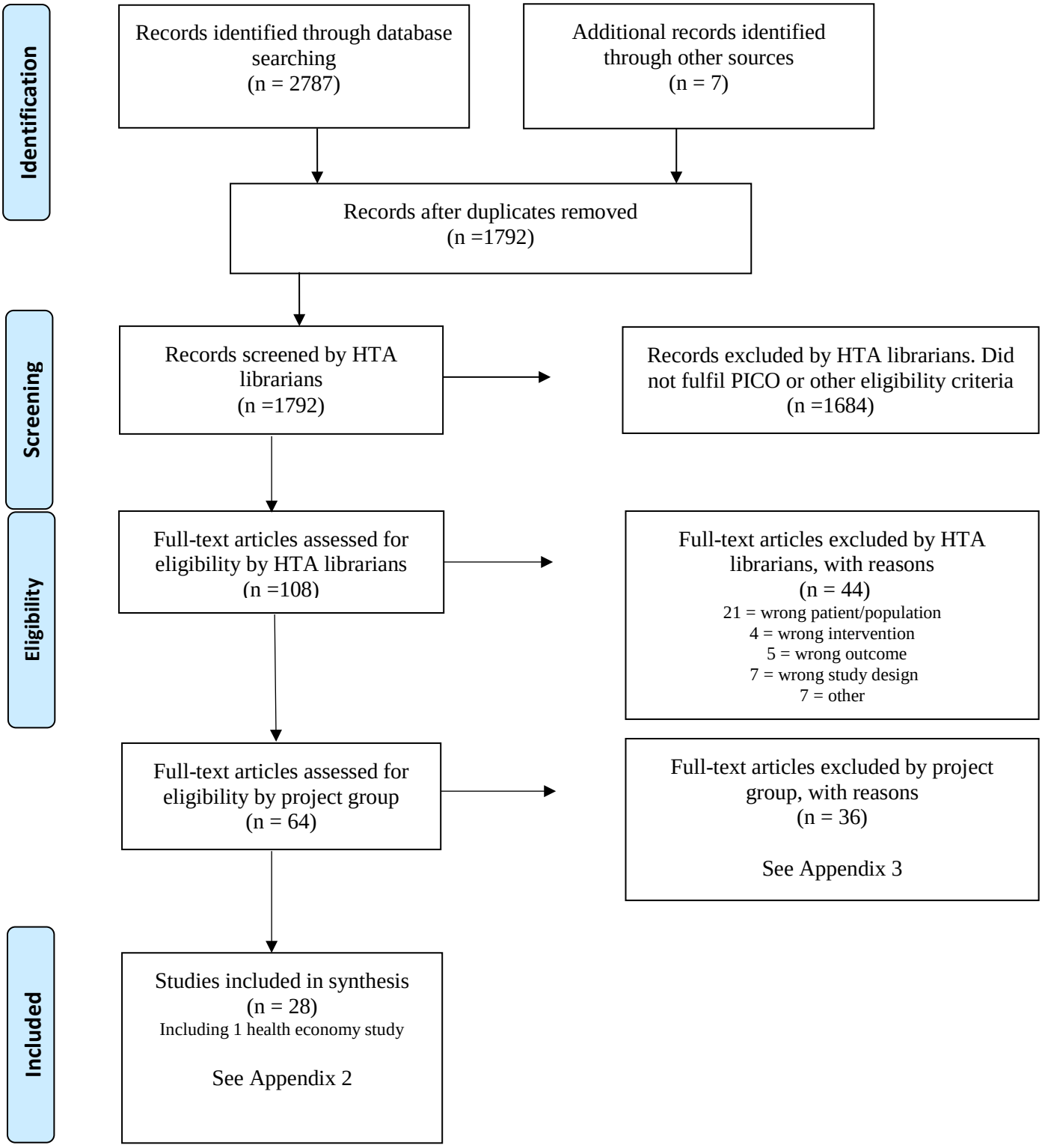
P	Pregnant women with a child in breech presentation, from gestational week 34+0.
I	Intention to deliver by Caesarean section
C	Intention to deliver vaginally
O	<u>Critical for decision making</u> Perinatal mortality Short term perinatal outcome (perinatal morbidity): stay at neonatal care unit, hypoxic ischemic encephalopathy (HIE), intracranial bleeding, asphyxia (Apgar score <7 at 5 minutes, pH ≤ 7.05, base excess (BE) ≤ -12, traumatic birth injury) Long term child outcome: neurodevelopmental or physical problems Maternal mortality Short term maternal outcome: infection, bleeding, thrombosis, delivery tract trauma Long term maternal outcome: pelvic floor dysfunction, placenta praevia/accrete and uterine rupture in subsequent pregnancies (All suggested morbidity outcomes are not critical, particularly surrogate outcomes are important, rather than critical, but they will be reported under the heading “Critical outcomes- morbidity”.) <u>Important but not critical for decision making</u> Conversion of delivery mode The mothers experience of delivery

Study design:
SR
RCT
Cohort studies >500/group
Case reports >1000 pat, Caesarean section and vaginal delivery

Year of publication:
1990-

Language:
English, Swedish, Danish, Norwegian

Selection process – flow diagram



Search strategies

Database: PubMed
Date: 2017-01-26
No of results: 810

Search	Query	Items found
#13	**Search #10 NOT #11 Filters: Publication date from 1990/01/01; Danish; English; Norwegian; Swedish**	**810**
#12	Search #10 NOT #11	1447
#11	Search (Editorial[ptyp] OR Letter[ptyp] OR Comment[ptyp])	1526558
#10	Search #8 NOT #9	1566
#9	Search ((animals[mh]) NOT (animals[mh] AND humans[mh]))	4291725
#8	Search #3 AND #6 AND #7	1568
#7	Search delivery[tiab] OR deliveries[tiab] OR birth[tiab] OR births[tiab] OR section[tiab] OR sections[tiab]	844064
#6	Search #4 OR #5	130141
#5	Search cesarean[tiab] OR caesarean[tiab] OR vaginal[tiab]	119197
#4	Search "Cesarean Section"[Mesh]	38990
#3	Search #1 OR #2	3315
#2	Search breech[ti]	2096
#1	Search "Breech Presentation"[Mesh]	2869

Database: Embase 1974 to 2017 January 25 (OvidSP)
Date: 2017-01-26
No of results: 1521

#	Searches	Results
1	exp breech presentation/	4374
2	breech.ti.	2078
3	1 or 2	4948
4	exp cesarean section/	80403
5	(cesarean or caesarean or vaginal).ab,ti.	158734
6	exp vaginal delivery/	25732
7	4 or 5 or 6	186674
8	(delivery or deliveries or birth or births or section or sections).ab,ti.	1045430
9	3 and 7 and 8	2783
10	(animal not (animal and human)).sh.	1326545
11	9 not 10	2782
12	**limit 11 to ((danish or english or norwegian or swedish) and yr="1990 -Current" and (article or conference paper or note or "review"))**	**1521**

Database: CINAHL (EBSCOhost)
Date: 2017-01-26
No of results: 335

#	Query	Results
S10	**S3 AND S7 AND S8** **Limiters – Published Date: 19900101-20171231** **Narrow by Language: english**	**335**
S9	S3 AND S7 AND S8	339
S8	TI (delivery or deliveries or birth or births or section or sections) OR AB (delivery or deliveries or birth or births or section or sections)	96,780
S7	S4 OR S5 OR S6	19,222
S6	(MH "Vaginal Birth+")	2,882
S5	TI (cesarean or caesarean or vaginal) OR AB (cesarean or caesarean or vaginal)	14,390
S4	(MH "Cesarean Section+")	9,038
S3	S1 OR S2	853
S2	TI breech	445
S1	(MH "Breech Presentation")	761

Database: The Cochrane Library
Date: 2017-01-26
No of results: 121
Cochrane reviews 15
Other reviews 6
Trials 92
Methods studies 2
Technology assessments 1
Economic evaluations 5

ID	Search	Hits
#1	MeSH descriptor: [Breech Presentation] explode all trees	125
#2	breech:ti,ab,kw (Word variations have been searched)	235
#3	#1 or #2	235
#4	MeSH descriptor: [Cesarean Section] explode all trees	2731
#5	cesarean or caesarean or vaginal:ti,ab,kw (Word variations have been searched)	15451
#6	#4 or #5	15451
#7	delivery or deliveries or birth or births or section or sections:ti,ab,kw (Word variations have been searched)	42005
#8	**#3 and #6 and #7 Publication Year from 1990 to 2017**	**121**

The web-sites of **SBU** and **Folkehelseinstituttet** were visited 2017-09-06. Nothing relevant to the question at issue was found.

Reference lists
A comprehensive review of reference lists brought 7 new records.

Reference lists

Included studies:

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Author Year Country	Study Design	Study Duration (years)	Study Groups; Intervention (I) vs control (C)	Patients (n before dropout)	Gest-ational age (weeks)	Mal-formations excluded	Outcome variables
Hannah 2000 Canada	RCT	1997-2000	I=planned CS (1043) C=planned vaginal birth (1045)	2088	>37	yes	perinatal morbidity and mortality maternal morbidity and mortality conversion
Hannah 2002 Canada	RCT	1997-2000	I=planned CS (798) C=planned vaginal birth (798)	1940	>37	yes	Child morbidity 28 days-2 years maternal morbidity mother experience
Hannah 2004 Canada	RCT	1997-2000	I=planned CS (457) C=planned vaginal birth (460)	1159	>37	yes	maternal morbidity, long term
Hodnett 2005 Canada	RCT	1997-2000	I=planned CS (457) C=planned vaginal birth (460)	1159	>37	yes	mother experience
Whyte 2004 Canada	RCT	1997-2000	I=planned CS (457) C=planned vaginal birth (463)	1159	>37	yes	long term child morbidity, >2 years
Bin 2016a Australia	Cohort	2001-2012	I=planned CS (11,339) C=planned vaginal birth (1183) (2,759 intention uncertain)	15281	>37	yes	child mortality and long term morbidity
Bin 2016b Australia	Cohort	2009-2012	I=planned CS (3970) C=planned vaginal birth (352) (875 intention uncertain)	10133	>37	yes	perinatal morbidity maternal morbidity
Burgos 2015 Spain	Cohort	2003-2012	I=planned CS (793) C=planned vaginal birth (891)	1684	>37	yes	perinatal morbidity and mortality
Gilbert 2003 USA	Cohort	1991-1999	I1=planned CS (60,418) I2=CS in labour (35,297) C=vaginal birth (4952)	100,667	>37	yes	perinatal morbidity and mortality
Goffinet 2006 France, Belgium	Cohort prospecti ve	2001-2002	I=planned CS (5579) C=planned vaginal birth (2526)	8105	>37	no	perinatal morbidity and mortality (composite outcome)
Hartnack 2011 Denmark	Cohort	1997-2008	I=planned CS (14,764) C=planned vaginal birth (7039)	23789	“term”	yes	perinatal morbidity and mortality
Herbst 2005 Sweden	Cohort	1991-2001	I=planned CS (9749) C=planned vaginal birth (6839) (Also cephalic vs breech presentation)	22549	>38	yes	perinatal morbidity and mortality, 1 year Study B is excluded, few cases

Author Year Country	Study Design	Study Duration (years)	Study Groups; Intervention (I) vs control (C)	Patients (n before dropout)	Gest-ational age (weeks)	Mal-formations excluded	Outcome variables
Krebs 2003 Denmark	Cohort	1982-1998	I1=planned CS (7503) I2= emergency CS (5575) C=actual vaginal birth (2363)	15441 (only nulliparous)	"term"	unclear	maternal mortality maternal morbidity, first year maternal morbidity, long term
Krebs 1995 Denmark	Cohort	1982-1990	I1=planned CS (7106) I2= emergency CS (5356) C=actual vaginal birth (2363)	15718	"term"	yes	perinatal morbidity and mortality
Mackay 2015 Scottland	Cohort	2006-2011	I=planned CS (12,489) C=planned vaginal birth (1574) (Also cephalic vs breech presentation)	14063	>37	unclear	perinatal morbidity long term child outcome
Pasupathy 2009 Scottland	Cohort	1985-2004	I1=planned CS (19,832) I2=pre-labour emergency CS (4108) I3= post-labour emergency CS (4910) C=planned vaginal birth (3926)	32776	>37	yes	perinatal mortality
Pradhan 2005 UK	Cohort	1991-2000	I=planned CS (552) C=planned vaginal birth (881)	1433	>37	no	perinatal mortality perinatal morbidity long term child morbidity >2 years
Rietberg 2003 The Netherlands	Cohort	1995-1999	I=planned CS (6840) C=planned vaginal birth (24,391) (208 unknown mode of delivery)	33824	>37	yes	perinatal morbidity and mortality
Rietberg 2005 The Netherlands	Cohort	1998-2002	I1=planned CS (8682) I2= emergency CS (2731) C=actual vaginal birth (2835) (Unknown mode of delivery=10)	14258	>37	yes	perinatal morbidity and mortality
Roman 1998 Sweden	Cohort	1987-1993	I1=planned CS (6031) I2= emergency CS (3011) I3=unspecified CS (879) C=actual vaginal birth (5897)	15,818	>37	yes	perinatal morbidity and mortality maternal morbidity and mortality
Thorpe-Beeston 1992 England	Cohort	1988-1990	I1=planned CS (1457) I2= emergency CS (1029) C=actual vaginal birth (961)	3447	>37	yes	perinatal morbidity and mortality
Ulander 2004 Finland	Cohort	1987-1989	I=planned CS (1640) C=planned vaginal birth (1,270)	2910 (in breech)	>37	yes	perinatal mortality perinatal morbidity, <28 days long term child morbidity, >2 years maternal morbidity and mortality

Author Year Country	Study Design	Study Duration (years)	Study Groups; Intervention (I) vs control (C)	Patients (n before dropout)	Gest-ational age (weeks)	Mal-formations excluded	Outcome variables
Venditelli 2006 France	Cohort	1994-2000	I=planned CS (879) C=planned vaginal birth (1216)	2136	>37	yes	perinatal morbidity and mortality conversion
Vistad 20015 Norway	Cohort	1991-2011	I=planned CS (13,361) C=planned vaginal birth (17,500) Also different time periods	30,861	"term"	yes	perinatal morbidity and mortality
Vlemmix 2014 The Netherlands	Cohort	1999-2007	I=planned CS (30503) C=planned vaginal birth (27,817) Also different time periods	58,320	37-41	yes	perinatal morbidity and mortality
Liu 2007 Canada	Case series	1991-2005	I=planned CS (46,766)	68,404	>37	yes	maternal morbidity and mortality
Schutte 2007 The Netherlands	Case series	2000-2002	Maternal deaths after elective CS for breech presentation	46,766	-	-	maternal mortality
Palencia 2006 Canada	Cost analysis	-	-	-	-	-	-

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 3. Excluded articles

Study Author Publication year	Reason for exclusion
Albrechtsen 1998	Intended mode of delivery not mentioned.
Albrechtsen 2000	Gestational week from 25. Does not compare delivery mode.
Andersen 2009	Intended mode of delivery not mentioned.
Azira 2012	Double publication with Goffinet -05.
Bergenhenegouwen 2014	Not correct PICO. Systematic review of preterm population.
Bergenhenegouwen 2015	Not correct PICO. Preterm population.
Bergenhenegouwen 2016	Not correct PICO.
Berhan 2016	Systematic review
Cahill 1991	Not correct PICO. Preterm population.
Daskalakis 2006	Planned vaginal delivery too few n= 392.
Demirci 2012	Planned vaginal delivery too few n= 478. Preterm population.
Eide 2005	Intended mode of delivery not mentioned.
Hehir 2012	Intended mode of delivery not mentioned.
Herbst 2007	Intended mode of delivery not mentioned.
Hinderaker 1994	Intended mode of delivery not mentioned.
Hoehner 2006	Intended mode of delivery not mentioned.
Hofmeyr 2015	Systematic review
Håheim 2004	Old systematic review

Project: Term breech presentation - Caesarean section versus vaginal delivery

Appendix 3. Excluded articles

Study Author Publication year	Reason for exclusion
Högberg 2016	Intended mode of delivery not mentioned.
Jensen 2015	Not correct PICO.
Kiely 1991	Intended mode of delivery not mentioned.
Krebs 1999	Intended mode of delivery not mentioned.
Lee 1998	Intended mode of delivery not mentioned.
Lindquist 1997	Intended mode of delivery not mentioned.
Lyons 2015	Intended mode of delivery not mentioned.
Mailath 2009	Too few ESEC n=304.
Mattila 2015	Too few vaginal delivery n= 406.
Pajntar 1994	Intended mode of delivery not mentioned.
Panagiotopoulou 2012	Not correct PICO, wrong outcome. Intended mode of delivery not mentioned.
Roberts 2000	Not correct PICO.
Robilio 2007	Not correct PICO. Preterm population.
Roman 2008	Not correct PICO. Risk factors for ASEC when VD was planned.
Su 2004	Not correct PICO. Secondary analysis of neonatal mortality risk factors.
Su 2003	Double publication
Su 2007	Not correct PICO. Secondary analysis of maternal morbidity risk factors.
Villar 2007	Not correct PICO. Analysis mainly of vertex delivery.

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.1
Outcome variable: Perinatal mortality

Author, year, country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Hannah 2000 Canada	RCT	2088	5	3/1039 (0.3%) RR 0.23 (95% CI 0.07; 0.81) p=0.01 Subgroup low national PMR 0/514 (0%) Subgroup high national PMR 3/525 (0.6%)	13/1039 (1.3%) Subgroup low national PMR 3/511 (0.6%) Subgroup high national PMR 10/528 (1.9%) When two stillbirths are excluded: 11/1038 (1.1%) RR 0.27 (95% CI 0.076-0.974) p=0.06		Perinatal mortality <28d 121 center, 26 countries Mortality or morbidity <28d Number 2 (a twin) and 15 in table 4 are excluded by us (stillbirths)	?	?(+)	?
Burgos 2015 Spain	Retro-spective cohort	1684	nr	0/793 (0%)	1/891 (0.11%)			+	?	?
					1/512 (0.20%)	0/379 (0%)				
Gilbert 2003 USA/ California	Retro-spective cohort	100,667	nr	25/60,481 (0.04%) 0.41/1,000	31/40,249 (0.07%)		4.9% vaginally delivered >37gw Compare with cephalic presentation vaginal delivery 0.03%	+	?	+
					9/4952 (0.18%)	22/35,297 (0.06%)				
Goffinet 2006 Belgium, France	Pro-spective cohort	8105	nr	Composite outcome 8/5,573 (0.14%)	Composite outcome 2/2502 (0.08%)		Fetal and neonatal mortality included. Deaths related to lethal malformation excluded. Composite outcome: neonatal mortality and serious morbidity	+	?	?
					nr/1796	nr				
Hartnack 2011 Denmark 1997- Oct2000	Retro-spective cohort	7101	nr	1/3667 (0.027%)	8/2938 (0.27%)		First period in the publication	+	?	?
Hartnack 2011 Denmark Oct 2000-2008	Retro-spective cohort	15,198	nr	1/11,097 (0.01%)	7/4101 (0.17%)		Second period in the publication	+	?	?

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.1
Outcome variable: Perinatal mortality

Author, year, country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	Directness *	Study limitations *	Precision *
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Herbst 2005 Sweden	Retro-spective cohort	22,549	nr	10/9,749 (0.01%)	26/12,800 (0.20%)			+	?	+
					19/6839 (0.28%)	7/5961 (0.12%)				
Krebs 1995 Denmark	Retro-spective cohort	15,718	nr	9/7,106 (0.13%)	26/8,603 (0.30%)			+	?	+
					12/3247 (0.37%)	14/5356 (0.26%)				
Pasupathy 2009 UK	Retro-spective cohort	32,776	nr	7/19,832 (0.04%)	25/12,944 (0.19%)		Death <28d	+	?	+
					11/3926 (0.28%)	14/9018 (0.16%)				
Pradhan 2005 UK	Retrospec tive cohort	1433	0	0/552 (0%)	4/881 (0.45%)		Small group from one centre 91-00. One lethal malformation was included. No difference in long term outcome, depending on delivery mode.	?	-	-
					3/416 (0.72%)	1/465 (0.22%)				
Rietberg 2003 The Netherlands	Retro-spective cohort	33,824	nr	<4000 g 7/4,151 (0.17%) >4000 g 0/540 (0%) Total: 7/4,691 (0.15%) Planned for other reasons: 14/2,689 (0.52%) >4000 g 2/276 (0.7%) OR 0.43 (95% CI 0.26-1.21)	<4000 g 95/24391 (0.39%) >4000 g 3/1,553 (0.2%) Total: 98/25,944 (0.38%)		Death <1 week post partum Vaginal delivery 50%! Lowest mortality in “planned CS because of breech”, highest in “planned CS because of other reasons” OR and 95% CI corrected for birthweight	?	?	+
					<4000 g 73/16,767 (0.43%) >4000 g 1/673 (0.1%) Total: 74/17,440 (0.42%)	<4000 g 22/7624 (0.29%) >4000 g 2/880 (0.2%) Total: 24/8504 (0.28%)				

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.1
Outcome variable: Perinatal mortality

Author, year, country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Rietberg 2005 The Netherlands	Retro-spective cohort	14,258	10	Breech 4/6773 (0.06%) Other 5/1909 (0.26%)	17/5566 (0.31%)		This is results only AFTER the TBT! Babies under 4000g. Drop outs = unknown mode of delivery. The rapid change after the TBT improved neonatal outcome.	+	?	?/+
					14/2835 (0.49%)	3/2731 (0.11%)				
					Nulliparous 11/339 (3.24%) Multiparous 14/665 (2.11%) Total 25/1004 (2.49%)	Nulliparous 12/2222 (0.54%) Multiparous				
Roman 1998 Sweden	Retro spective cohort	15,818	nr	9/6031 (0.15%)	24/8908 (0.27%)		Infant mortality < 12 months One group not reported here: unspecified CS 3/879 (0.34%)	+	+	?
					18/5897 (0.31%)	6/3011 (0.20%)				
Thorpe-Beeston 1992 UK	Retro-spective cohort	3447	nr	0 or 1/1457	nr		Death <28d 1 dead after CS but unclear if it was elective or emergency CS.	+	?	?
					8/961 (0.83%)	0 or 1/1029				
Ulander 2004 Finland	Retro-spective cohort	2910	nr	0/1640 (0%)	1/1270 (0.08%)		Study compare differences according to presentation, not delivery mode. Not divided into actual vaginal and emergency CS.	+	?	-
Vendittelli 2006 France	Retro-spective cohort	2,095	41	1/879 (0.11%)	1/1216 (0.08%)		Mortality intra- or ”immediate” post-partum (time??)	+	+/?	-

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.1
Outcome variable: Perinatal mortality

Author, year, country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Vistad 2015 Norway	Retro-spective cohort	30,861	nr	8/13,361 (0.06%)	25/17,500 (0.14%)		Death <28d Subgroups before and after the TBT are compared. "Planned vaginal breech delivery had a higher risk of adverse neonatal outcome."	+	+/?	+
Vlemmix 2014 The Netherlands	Retro-spective cohort	58,320	nr	0/30,503 (0%)	46/27,817 (0.17%)		Death <7d The Netherlands 99-07. Subgroups before and after the TBT are compared, also nulliparous/multiparous	+	+/?	+/?
					28/16,323 (0.17%)	18/11,494 (0.16%)				

CS= Caesarean section, d=days, gw= Gestational weeks, nr=not reported, PMR= Perinatal mortality rate, RCT= Randomised controlled trial, TBT= Term breech trial

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.2
Outcome variable: Child morbidity, short term <28d

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	Directness *	Study limitations *	Precision *
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Hannah 2000 Canada	RCT	2088	5	Perinatal/neonatal mortality or serious neonatal morbidity 17/1039 (1.6%) Only low national PMR 2/514 (0.4%) Serious neonatal morbidity 14/1036 (1.4%) R0.36 (95%CI 0.19-0.65) Only low national PMR 2/514 (0.4%) 5-min Apgar <7 8/1000 (0.8%) NICU≥4 days 4/1000 (0.4%) Traumatic birth injury 6/1000 (0.6%)	Perinatal/neonatal mortality or serious neonatal morbidity* 50/1038 (5.0%) Only low national PMR 29/511 (5.7%) Serious neonatal morbidity 39/1026 (3.8%) R0.36 (95%CI 0.19-0.65) Only low national PMR 26/508 (5.1%) 5-min Apgar <7 31/1033(3.0%) NICU≥4 days 6/1000 (0.6%) Traumatic birth injury 14/1000 (1.4%)		121 center, 26 countries Primary outcome is a composite score = perinatal/neonatal mortality or serious neonatal morbidity <28 days Serious neonatal morbidity: birth trauma, seizures, hypotonia, abnormal level of consciousness, low Apgar score, abnormal cord-blood values, intubation and ventilation, tube feeding, care in NICU * Result when number 2 (a twin) and 15 in table 4 are excluded by us (stillbirths)	?	?	?
Bin 2016b Australia	Retro-spective cohort	5197		3970 Neonatal Morbidity and mortality 2.1% Neonatal birth trauma 0.9% 5-minute Apgar<7 0.5% NICU admission 6.6%	352 (134 CS) Neonatal Morbidity and mortality 6% Neonatal Birth trauma 7.4% 5-minute Apgar<7 4.3% NICU admission 16.2%		6.8% intended vaginal breech Intention uncertain 875	+	?	?

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.2
Outcome variable: Child morbidity, short term <28d

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Burgos 2015 Spain	Retro-spective cohort	2377		Mean umbilical arterial cord ph 7.25 (sig) Umbilical cord arterial ph<7 6/793 (0.7%) (p<0.01) BE<-12 13/793 (1.7%) (p<0.01) 5-min Apgar <7 31/793 (0.4%) (p<0.01) Admission to NICU 16/793 (2%) (p<0.86) Intrapartum perinatal composite morbidity 0/793 (0%) (p=1)	Mean umbilical arterial cord ph 7.19 Umbilical cord arterial ph <7 27/891 (3.0%) BE<-12 106/891 (11.9%) 5-min Apgar <7 20/891 (2.2%) Admission to NICU 20/891 (2.2%) Intrapartum perinatal composite morbidity 1/891 (0.1%)		Intrapartum perinatal composite morbidity = Umbilical cord arterial ph <7 + BE<-12 + 5-min apgar <7 + Admission to NICU	+	?	?
					Mean umbilical arterial cord ph 7.18 Umbilical cord arterial ph <7 1/512 (2.4%) BE<-12 74/512 (14.5%) 5-min Apgar <7 15/512 (2.9%) Admission to NICU 11/512 (2.1%) Intrapartum perinatal composite morbidity 0/512 (0%)	Mean umbilical arterial cord ph 7.21 Umbilical cord arterial ph <7 14/379 (3.8%) BE<-12 33/379 (8.8%) 5-min Apgar <7 5/379 (1.3%) Admission to NICU 8/379 (2.2%) Intrapartum perinatal composite morbidity 1/379 (0.3%)				

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.2
Outcome variable: Child morbidity, short term <28d

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	Directness *	Study limitations *	Precision *
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Goffinet 2006 Belgium, France	Pro-spective cohort	8105		5-min Apgar <7 0.46% Traumatic birth injury 0.46% Transfer to NICU 1.63% NICU >4days 0.95% IVH 0.04% Convulsions 0.13%	5-min Apgar <7 1.8% Traumatic birth injury 1.8% Transfer to NICU 2.16% NICU >4days 0.92%+ IVH 0.04% Convulsions 0.16%			+	?	?
Hartnack 2011 Denmark 1997- oct 2000	Retro-spective cohort	7101		5- minute Apgar ≤6 18/3667 (0.49%) NICU≥4 days 143/3667 (3.40%)	5- minute Apgar ≤6 52/2938 (1.77%) NICU≥4 days 129/2938 (4.39%)		Retrospective cohort comparing two time periods were the caesarian section rate went from 79.6% to 94.2% and the death rate went from 0.13% to 0.05% in all term breech presentations regardless mode of delivery	+	?	?
Hartnack 2011 Denmark Oct 2000-2008	Retro-spective cohort	15,198		5- minute Apgar ≤6 36/11097 (0.32%) NICU≥4 days 314/11,097 (2.83%)	5- minute Apgar ≤6 60/4101 (1.46%) NICU≥4 days 175/4101 (4.27%)		Retrospective cohort comparing two time periods were the CS rate went from 79.6% to 94.2% and the death rate went from 0.13% to 0.05% in all term breech presentations regardless mode of delivery	+	?	?
Herbst 2005 Sweden	Retro-spective cohort	20,233		5-minute Apgar<7 62/7574 (0.82%)	5-minute Apgar<7 288/12781 (2.25%)			+	?	+
Krebs L 1995 Denmark	Retro-spective cohort	15,718		5-minute Apgar<7 20/7106 (0.28%)	5-min Apgar<7 66/3247 (2.03%)	5-min Apgar<7 61/535 (1.14%)		+	?	+

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.2
Outcome variable: Child morbidity, short term <28d

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	Directness *	Study limitations *	Precision *
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Mackay 2015 Scottland	Retro-spective cohort	14,063 Breech	115 vs 11	5-min Apgar <4 44/12,489 (0.35%) 5-min Apgar <7 89/12,374 (0.72%) OR 0.62 (95% CI 0.50; 0.77)	5-min Apgar <4 23/1574 (1.46%) 5-min Apgar <7 70/1563 (4.48%)		At term (≥37+0) singletons in breech. OR adjusted for infant sex, maternal age, maternal height, marital status, area deprivation index, parity, birthweight centile, pervious spontaneous and therapeutic abortions, estimated gestational age, smoking during pregnancy and year of delivery	+	?	+
Pradhan 2005 UK	Retro-spective cohort	1433	5.7%	5 min Apgar <7 5/552 (0.9%) Neonatal unit 9/552 (1.6%) Neonatal convulsions 0/552 Traumatic birth injury 0/552 (0%)	5 min Apgar <7 52/881 (5.9%) Neonatal unit 36/881 (4.0%) Neonatal convulsions 2/881 (0.2%) Traumatic birth injury 0/881		Vaginal delivery and Emergency CS is the same group.	?	?	-

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.2
Outcome variable: Child morbidity, short term <28d

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Rietberg 2003 The Netherlands	Retro-spective cohort	33,824		5 min Apgar <7 <4000g 18/4151 (0.43) >4000g 0/540 (0%) Traumatic birth injury <4000g 7/4151 (0.17%) >4000g 0/540 (0%) Planned for other reasons 5 min Apgar <7 <4000g 44/2689 (1.64) >4000g 2/276 (0.7%) Traumatic birth injury <4000g 3/2689 (0.11%) >4000g 0/276 (0%)	5 min Apgar <7 <4000 g 690/24391 (2.83%) >4000 g 31/1553 (2.0) Traumatic birth injury <4000 g 122/24391 (0.50%) >4000 g 9/1553 (0.6)		Many subgroups.	?	?	?
					5 min Apgar <7 <4000g 523/16767 (3.12%) >4000g 19/673 (2.8%) Traumatic birth injury <4000g 105/16767 (0.63%) >4000g 9/673 (1.3%)	5 min Apgar <7 <4000g 167/7624 (2.19%) >4000g 12/880 (1.4%) Traumatic birth injury <4000g 17/7624 (0.22%) >4000g 0/880 (0%)				

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.2
Outcome variable: Child morbidity, short term <28d

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	Directness *	Study limitations *	Precision *
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Rietberg 2005 The Netherlands	Retro-spective cohort	14,258	10 (0.07%) mode of delivery not coded	5 min Apgar <7 22/6773 (0.33%) Traumatic birth injury 3/6773 (0.04%) Planned for other reasons Apgar<7 13/1909 (0.68%) Neonatal trauma 1/1909 (0.05%)	5 min Apgar <7 73/2835 (2.57%) Traumatic birth injury 6/12835 (0.21%)	5 min Apgar <7 41/2731 (1.50%) Traumatic birth injury 1/2731 (0.04%)	This is results only AFTER the TBT. Babies under 4000g. Subgroups; planned CS because of breech or other reasons, actual vaginal delivery/ emergency CS, before and after the term breech trial The overall analysis is before and after the TBT, not according to mode of delivery.	-	?/-	?/+
Roman 1998 Sweden	Retro-spective cohort	15,818		5 min Apgar <7 19/6031 (0.3%) Traumatic birth injury 13/6031 (0.2%) Convulsions 5/6031 (0.08%)	5 min Apgar <7 163/5897 (2.8%) Traumatic birth injury 155/5897 (2.6%) Convulsions 12/5897 (0.2%)	5 min Apgar <7 45/3011 (1.5%) Traumatic birth injury 13/3011 (0.4%) Convulsions 12/3011 (0.4%)	One group not reported here: unspecified CS, n=879	+	+	+

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.2
Outcome variable: Child morbidity, short term <28d

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	Directness *	Study limitations *	Precision *
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Thorpe-Beeston 1992 The Netherlands	Retro-spective cohort	3447		5 min Apgar <7 32/1457 (2.2%) RR 0.5 (95% CI 0.3; 0.77) Intubation RR 0.45 (95% CI 0.34; 0.62) 61/1457 (4.2%) Special care baby unit 75/1457 (5.1%) RR 0.83 (95% CI 0.6; 1.1)	5 min Apgar <7 88/1990 (4.42%) Intubation 184/1990 (9.25%) Special care baby unit 126/1990 (6.33%)		Reports RR for planned vaginal delivery vs planned CS. Here inverted to CS vs vaginal	?	-	-
					5 min Apgar<7 44/961 (4.6%) Intubation 86/961 (8.9%) Special care baby unit 54/961 (5.6%)	5 min Apgar<7 44/1029 (4.3%) Intubation 98/1029 (9.5%) Special care baby unit 72/1029 (7.0%)				
Ulander 2004 Finland	Retro-spective cohort	2910		<7 days: Traumatic birth injury 5/1640 (0.3%) Hypoxi 20/1640 (1.2%) Apgar<7 at 5 min 2/1640 (0.4%) Intracranial hemorrhage 0/1640 (0.0%) Respiratory problems 15/1640 (0.9%)	<7 days: Traumatic birth injury 41/1270 (3.2%) Hypoxi 84/1270 (6.6%) Apgar<7 at 5 min 28/1270 (2.2%) Intracranial hemorrhage 1/1270 (0.1%) Respiratory problems 9/1270 (0.7%)		Study compares differences according to presentation, not delivery mode. Not divided into actual vaginal and emergency CS.	+	+	?

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.2
Outcome variable: Child morbidity, short term <28d

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	Directness *	Study limitations *	Precision *
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Vendittelli 2006 France	Retro-spective cohort	2095	41	Resuscitation in maternity ward 51/879 (5.8%) Apgar at 5 min <4 2/879 (0.24%) Apgar at 5 min <7 4/879 (0.47%) Traumatic birth injury 1/879 (0.11%) Transfer to neonatal unit, surgery unit or intensive care unit 91/987 (10.3%) Mortality or transfer to NICU or surgery 17/879 (1.9%)	Resuscitation in maternity ward (9.4%) Apgar at 5 min <4 (0.09%) Apgar at 5 min <7 14/1216 (1.18%) Traumatic birth injury 8/1216 (0.66%) Transfer to neonatal unit, surgery or intensive care unit 80/879 (9.1%) Mortality or transfer to NICU or surgery 20/879 (2.3%)		Compares groups according to *planned* mode of delivery. Adjustment for maternal age, BMI, parity, pregnancy-related disorders, type of breech; OR 0.75 (95% CI 0.35; 1.58) (inverted to the comparison CS vs vaginal) Primary outcome = Mortality or transfer to NICU or surgery	+	+/?	+
Vistad 2015 Norway	Retro-spective cohort	30,861		5 min Apgar <7 70/13361 (0.52%) Intensive care unit stay >4d (only period 2 available) 191/8290 (2.3%) Respiratory morbidity (only period 2 available) 10/8290 (0.1%) Intracranial bleeding disorders (only period 2 available) 1/8290 (0.01%)	5 min Apgar <7 428/17479 (2.45%) Intensive care unit stay >4d (only period 2 available) 322/7887 (4.1%) Respiratory morbidity (only period 2 available) 18/7887 (0.2%) Intracranial bleeding disorders (only period 2 available) 11/7887 (0.1%)		Subgroups before and after the TBT are compared in the article. Here the time periods are combined.	+	+	+
Vlemmix 2014 The Netherlands	Retro-spective cohort	58,320		5 min Apgar <7 78/30503 (0.26%) Traumatic birth injury 27/30503 (0.09%)	5 min Apgar <7 452/16323 (2.77%) Traumatic birth injury 118/16323 (0.72%)	5 min Apgar <7 159/11494 (1.38%) Traumatic birth injury 18/11494 (0.16%)	Subgroups before and after the TBT are compared in the article. Here the subgroups are combined.	+	?	?

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.2
Outcome variable: Child morbidity, short term <28d

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	Directness *	Study limitations *	Precision *
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				

BE= Base excess
ASQ=Ages and Stages Questionnaire
CS=Caesarean Section
TBT=Term Breech Trial
IVH= Intraventricular hemorrhage
NICU= Neonatal Intensive Care Unit
PMR= perinatal mortality rate

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.3
Outcome variable: Child morbidity 28 days-2 years

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Hannah 2002 Canada	RCT	1940	344	n=798 Breastfed at 3 months 533/781 (68.3%) Visited physician after birth 147/736 (20.0%) Readmitted to hospital 20/730 (2.7%)	n=798 Breastfed at 3 months 539/776 (69.5%) Visited physician after birth 146/735 (19.9%) Readmitted to hospital 29/727 (4.0%)		3 months follow up of the TBT.	?	?	-
					n=456 Breastfed at 3 months 325/445 (73.0%) Visited physician after birth 76/416 Readmitted to hospital 17/409 (4.2%)	n=342 Breastfed at 3 months 214/331 (64.7%) Visited physician after birth 70/319 (21.9%) Readmitted to hospital 12/318 (3.8%)				

CS= Caesarean section
TBT= Term breech trial

Project: Term breech presentation – Caesarean section versus vaginal delivery
Appendix 4.4
Outcome variable: Child morbidity, long term >2 years

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Whyte 2004 Canada	RCT	1159	236	Death or neurodevelopmental delay 14/457 (3.1%) (2 deaths) Abnormal ASQ 40/415 (9.6%) Medical problems in the past months 86/415 (20.8%) Something about child is worrying 40/415 (9.7%)	Death or neurodevelopmental delay 13/463 (2.8%) (6 deaths) Abnormal ASQ 38/428 (8.9%) Medical problems in the past months 63/428 (14.7%) Something about child is worrying 47/428 (11.0%)		2-year follow up of Hannah ASQ= Ages and Stages Questionnaire	?	-	-
Bin 2016a Australia	Retro-spective cohort	15,281		Developmentally vulnerable* 298/1909 (15.6%) Special needs 92/1909 (4.8%) Low reading score** 491/2641 (18.6%) Low numeracy score** 412/2641 (15.6%) Hospitalisation between first and sixth birthday 3436/11339 (30.3%)	Developmentally vulnerable* 33/176 (19.3%) Special needs 8/176 (4.6%) Low reading score** 47/318 (14.8) Low numeracy score*** 57/318 (17.9%) Hospitalisation between first and sixth birthday 338/1183 (28.6%)		*Developmentally outcome median follow up 5 years **Educational outcome median follow up 8 years	+	?	?

Project: Term breech presentation – Caesarean section versus vaginal delivery
Appendix 4.4
Outcome variable: Child morbidity, long term >2 years

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Mackay 2014 Scotland	Retro-spective cohort	14,068 Breech (45,6947 including both breech and cephalic)		Additional support needs incl Autistic spectrum disorder 971/12,489 (7.8%) Additional support needs exl Autistic spectrum disorder 896/12,489 (7.2%) Highest examination attainment: Low 335/5826 (5.8%) Basic 1971/5826 (33.8%) Broad general 1482/5826 (25.4%) High 2038/5826 (35.0%)	Additional support needs incl Autistic spectrum disorder 133/1574 (8.5%) Additional support needs exl Autistic spectrum disorder 124/1574 (7.9%) Highest examination attainment: Low 82/1065 (7.7%) Basic 421/1065 (39.5%) Broad general 244/1065 (22.9%) High 318/1065 (29.9%)		Follow up of maximum 18 years of age	+	?	+
Pradhan 2005 Great Britain	Retro-spective cohort	1433	5.7%	Special needs and special educational needs 18/462 (3.8%) Cerabral palsy 0/462 (0%)	Special needs and special educational needs 36/669 (5.3%) Cerebral palsy 1/669 (0.1%)		Vaginal delivery and Emergency CS is the same group.	?	?	-
Ulander 2004 Finland	Retro-spective cohort	2910	?	7 year follow up: Any long term medication 29/511 (5.7%) Epilepsy 2/511 (0.4%) Asthma 25/511 (4.9%) Diabetes 2/511 (0.4%) Intellectual disability 15/511 (2.9%)	7 year follow up: Any long term medication 14/350 (4.0%) Epilepsy 1/350 (0.3%) Asthma 14/511 (4.0%) Diabetes 1/350 (0.3%) Intellectual disability 4/350 (1.1%)		Study compare differences according to presentation, not delivery mode. Not divided into vaginal delivery and emergency CS groups.	+	+	?

CS= Caesarean Section
PMR= Perinatal Mortality Rate

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.5
Outcome variable: Maternal mortality

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Hannah 2000 Canada	RCT	2088	5	0/1041 (0%)	1/1042 (0.1%)		121 center, 26 countries Mortality or morbidity <28d	?	?	?
Krebs 2003 Denmark	Retro-spective cohort	15,441		0/7503	3/7938 (0.04%)		Obstetric causes as described in the text is not in direct correlation to the intended vaginal breech delivery but two of them were associated with PE and one with VTE	+	?	+
					0/2363	3/5575 (0.05%)				
Roman 1998 Sweden	Retro-spective cohort	15,818		0/6031				+	+	?
					0/5897	0/3011				
Ulander 2004 Finland	Retro-spective cohort	2910		0/1640 (0%)	0/1270		Emergency CS not specified	+	?	?
Liu 2007 Canada	Case series	68,404		0/46,766	-		The study compares low risk cesarean due to breech with planned vaginal delivery without respect to presentation			
Schutte 2007 The Netherlands	Case series	16,351		3/8599 (0.04%)			Analysed all maternal deaths in the Netherlands 00-02 (n 95). Case series, only 4 maternal deaths.	-	-	?
						1/7752 (0.01%)				

CS= Caesarean section
d= days

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.6
Outcome variable: Maternal morbidity, first year

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Hannah 2000 Canada	RCT	2088	5	Maternal mortality or serious morbidity <28d 41/1041 (3.9%) (0 deaths in this group)	Maternal mortality or serious morbidity <28d 33/1042 (3.2%), p=0.35 (1 death in this group)		121 center, 26 countries Mortality or morbidity <6w Serious morbidity: post-partum bleeding >1000ml, genital tract injury, wound infection, dehiscence or breakdown, systematic infection, early post-partum depression	?	?(+)	?
Hannah 2002 Canada	RCT	1940	344	Pain during sex 111/655 (17.0%) Any pain 217/796 (27.3%) Experienced urinary incontinence 36/798 (4.5%) Experienced faecal incontinence 5/619 (0.8%) Experienced flatus incontinence 66/616 (10.7%) Postpartum depression 80/793 (10.1%)	Pain during sex 126/674 (18.7%), p=0.43 Any pain 199/797 (25.0%), p=0.31 Experienced urinary incontinence 58/797 (7.3%), p=0.02 Experienced faecal incontinence 9/607 (1.5%), p=0.29 Experienced flatus incontinence 59/606 (9.7%), p=0.64 Postpartum depression 86/793 (10.8%), p=0.68		3 months follow up of the TBT	?	?	-
Bin 2016b Australia	Retro-spective cohort	10,133		Severe maternal morbidity 28/3970 (0.7%) Post-partum hemorrhage 132/3970 (3.3%) Post-partum readmission 157/3970 (4.0%)	Severe maternal morbidity 5/352 (1.4%) Post-partum hemorrhage 23/352 (6.5%) Post-partum readmission 16/352 (4.6%)			+	?	?

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.6
Outcome variable: Maternal morbidity, first year

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Krebs 2003 Denmark	Retro-spective cohort	15,441		Anemia and/or hemorrhage 430/7503 (5.7%) Puerperal fever/pelvic infection 110/7503 (1.5%) Wound infection (operated) 65/7503 (0.9%) Bladder injury 5/7503 (0.1%) VTE 6/7503 (0.1%) Rupture of anal sphincter 0	Anemia and/or hemorrhage 142/2363 (6.0%) Puerperal fever/pelvic infection 12/2363 (0.5%) Wound infection (operated) 16/2363 (0.7%) Bladder injury 0 VTE 0 Rupture of anal sphincter 41/2363 (1.7%)	Anemia and/or hemorrhage 397/5575 (7.0%) Puerperal fever/pelvic infection 126/5575 (2.3%) Wound infection (operated) 98/5575 (1.8%) Bladder injury 10/5575 (0.2%) VTE 7/5575 (0.1%) Rupture of anal sphincter 0	Until 6 weeks pp	+	?	+

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.6
Outcome variable: Maternal morbidity, first year

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Roman 1998 Sweden	Retro-spective cohort	15,818	?	3rd-degree laceration 0/6031 (0%) 4rd-degree laceration 0/6031 (0%) Severe vaginal rupture 0/6031 (0%) Severe puerperal infection 57/6031 (0.90%) Thrombosis 1/6031 (0.02%) Wound rupture 1/6031 (0.02%) Wound infection/bleeding 45/6031 (0.70%) Complications in total104/6031 (1.70%)	3rd-degree laceration 61/8908 (0.69%) 4rd-degree laceration 6/8908 (0.07%) Severe vaginal rupture 14/8908 (0.16%) Severe puerperal infection 65/8908 (0.73%) Thrombosis 1/8908 (0.01%) Wound rupture 7/8908 (0.08%) Wound infection/bleeding 38/8908 (0.43%) Complications in total 192/8908 (2.16%)			+	+	?
					3rd-degree laceration 60/5897 (1.00%) 4rd-degree laceration 6/5897 (0.10%) Severe vaginal rupture 13/5897 (0.02%) Severe puerperal infection 11/5897 (0.02%) Thrombosis 1/5897 (0.12%) Wound rupture 7/5897 (0.12%) Wound infection/bleeding 9/5897 (0.15%) Complications in total 107/5897 (1.80%)	3rd-degree laceration 1/3011 (0.03%) 4rd-degree laceration 0/3011 (0.00%) Severe vaginal rupture 1/3011 (0.03%) Severe puerperal infection 54/3011 (1.80%) Thrombosis 0/3011 (0.00%) Wound rupture 0/3011 (0.00%) Wound infection/bleeding 29/3011 (1.00%) Complications in total 85/3011 (2.80%)				

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.6
Outcome variable: Maternal morbidity, first year

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Ulander 2004 Finland	Retro-spective cohort	2910	?	Laparotomy 0/1640 (0%) Re-laparotomy 1/1640 (0.6%) Other invention 2/1640 (1.2%) Thrombosis 5/1640 (3.0%) Pulmonary embolism 0/1640 (0%)	Suture of perineum or vagina 17/1270 (13.4%) Suture of cervix 1/1270 (0.7%) Laparotomy 0/1270 (0%) Re-laparotomy 0/1270 (0%) Revision of haematoma 1/1270 (0.7%) Thrombosis 2/1270 (0.2%) Pulmonary embolism 0/1270 (0%)			+	?	?
Lui 2007 Canada	Case series	46,766		Overall severe morbidity: 1279/46,766 (2.73%) Hemorrhage requiring hysterectomy: 12/46,766 (0.03%) Hemorrhage requiring transfusion: 11/46,766 (0.02%) Any hysterectomy: 27/46,766 (0.06%) Uterine rupture: 7/46,766 (0.02%) Anesthetic complications: 247/46,766 (0.53%) Obstetric shock: 3/46,766 (0.01%) Cardiac arrest: 89/46,766 (0.19%) Acute renal failure: 2/46,766 (0.004%) Assisted ventilation or intubation : 6/46,766 (0.01%) Puerperal venous TE : 28/46,766 (0.06%) Major puerperal infection: 281/46,766 (0.6%) In-hospital wound disruption: 41/46,766 (0.09%) Obstetric wound hematoma: 601/46,766 (1.3%) In-hospital death: 0/46,766			Case series of planned low risk cesarean due to breech			

CS= Caesarean section
TBT= Term Breech Trial

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.7
Outcome variable: Maternal morbidity, long term

* + No or minor problems
? Some problems
\- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Hannah 2004 Canada	RCT	917	1171	n=457 Any pain during sex 42/457 (9.2%) Pain on outside of abdomen 20/457 (4.4%) Pain deep inside abdomen 23/457 (5.0%) Pain in bottom or genital area 15/457 (3.3%) Major urinary incontinence 3/457 (0.7%) Major faecal incontinence 1/457 (0.2%) Major flatus incontinence 5/457 (1.1%)	n=460 Any pain during sex 43/460 (9.4%), p=0.84 Pain on outside of abdomen 14/460 (3.0%), p=0.30 Pain deep inside abdomen 27/460 (5.9%), p=0.66 Pain in bottom or genital area 20/460 (4.4%), p=0.49 Major urinary incontinence 9/460 (2.0%) Major faecal incontinence 3/460 (0.7%) Major flatus incontinence 2/460 (0.4%)		2 years follow up of the TBT.	?	-	?
					Any pain during sex 25/257 (9.7%) Pain on outside of abdomen 5/257 (2%) Pain deep inside abdomen 11/257 (4.3%) Pain in bottom or genital area 16/257 (6.3%) Major urinary incontinence 4/257 (1.6%) Major faecal incontinence 1/257 (0.4%) Major flatus incontinence 2/257 (0.8%)	Any pain during sex 18/203 (8.9%) Pain on outside of abdomen 9/203 (4.4%) Pain deep inside abdomen 16/203 (7.9%) Pain in bottom or genital area 4/203 (2.0%) Major urinary incontinence 5/203 (2.5%) Major faecal incontinence 2/203 (1.0%) Major flatus incontinence 0/203 (0%)				

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.7
Outcome variable: Maternal morbidity, long term

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Krebs 2003 Denmark	Retro-spective cohort	10,588		Placenta praevia 5/4924 (0.1%) Ablatio 19/4924 (0.4%) Uterine rupture 5/4924 (0.1%) Placental/uterine complications 29/4924 (0.6%)	Placenta praevia 1/1790 (0.06%) Ablatio 6/1790 (0.3%) Uterine rupture 0/1790 (0%) Placental/uterine complications 7/1770 (0.4%)	Placenta praevia 3/3894 (0.08%) Ablatio 25/3894 (0.6%) Uterine rupture 2/3894 (0.05%) Placental/uterine complications 30/3894 (0.8%)	Complications in second or third pregnancy	+	?	+

CS= Caesarean section
TBT= Term Breech Trial

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.8
Outcome variable: Conversion of delivery mode

* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Hannah 2000 Canada	RCT	2088	5	100/1041 (9.6%) 95% CI 7.8%; 11.6%	451/1042 (43.3%) 95% CI 40.3%; 46.3%			?	?	+
Burgos 2015 Spain	Retrospective cohort	2377			379/891 (42.5%) 95% CI 39.3%; 45.8%			+	?	?
Vendettelli 2006 France	Retrospective cohort	2095	41		559/1216 (46%) 95% CI 43.2%; 48.8%			+	?	?

Project: Term breech presentation - Caesarean section versus vaginal delivery
Appendix 4.9
Outcome variable: Mother's experience of delivery

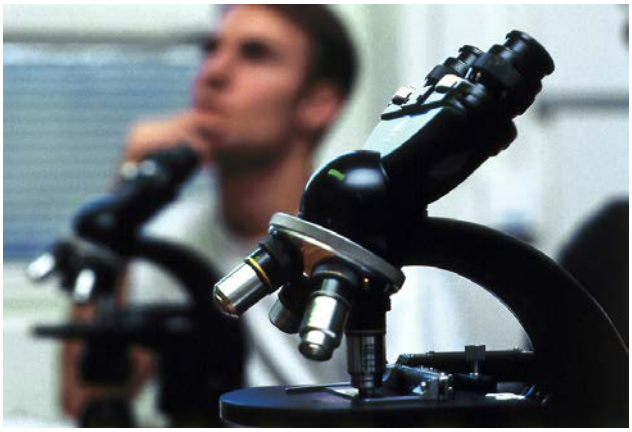
* + No or minor problems
? Some problems
- Major problems

Author year country	Study design	Number of patients n=	With drawals - dropouts	Results			Comments	* Directness	* Study limitations	* Precision
				Intended caesarean section (CS)	Intended vaginal delivery					
					Actual vaginal	Emergency CS				
Hannah 2002 Canada	RCT	1940	344	Liked nothing about childbirth experience 37/798 (4.6%) Disliked nothing about childbirth experience 334/798 (41.9%)	Liked nothing about childbirth experience 37/798 (4.6%) Disliked nothing about childbirth experience 325/798 (40.7%)		3 months follow up of the TBT	?	?	-
					Liked nothing about childbirth experience 15/456 (3.3%) Disliked nothing about childbirth experience 245/456 (53.7%)	Liked nothing about childbirth experience 22/342 (6.4%) Disliked nothing about childbirth experience 80/342 (23.4%)				
Hodnett 2005 Canada	RCT			Liked nothing about childbirth experience 27/457 (5.9%) Disliked nothing about childbirth experience 191/457 (41.8%) Liked the method of delivery 274/457 (60%)	Liked nothing about childbirth experience 25/460 (5.4%) Disliked nothing about childbirth experience 182/460 (39.6%) Liked the method of delivery 254/460 (55.2%)		2 years follow up of the TBT	?	-	?

CS= Caesarean section
TBT= Term Breech Trial

Region Västra Götaland, HTA-centrum

Health Technology Assessment
Regional activity-based HTA



HTA

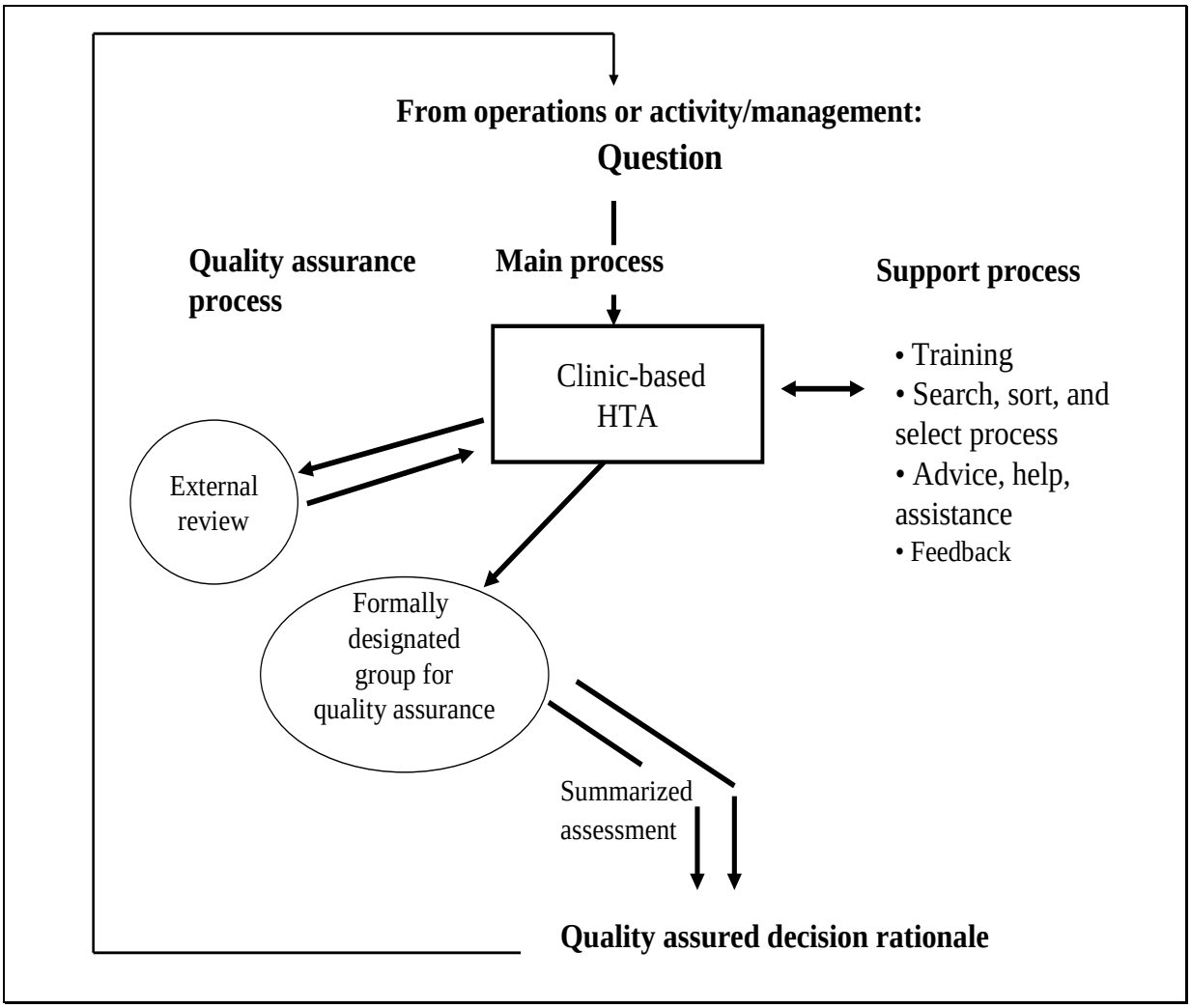
Health technology assessment (HTA) is the systematic evaluation of properties, effects, and/or impacts of health care technologies, i.e. interventions that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. It may address the direct, intended consequences of technologies as well as their indirect, unintended consequences. Its main purpose is to inform technology-related policymaking in health care.

To evaluate the quality of evidence the Centre of Health Technology Assessment in Region Västra Götaland is currently using the GRADE system, which has been developed by a widely representative group of international guideline developers. According to GRADE the level of evidence is graded in four categories:

High quality of evidence	= (GRADE⊕⊕⊕⊕)
Moderate quality of evidence	= (GRADE ⊕⊕⊕O)
Low quality of evidence	= (GRADE ⊕⊕OO)
Very low quality of evidence	= (GRADE ⊕OOO)

In GRADE there is also a system to rate the strength of recommendation of a technology as either “strong” or “weak”. This is presently not used by the Centre of Health Technology Assessment in Region Västra Götaland. However, the assessments still offer some guidance to decision makers in the health care system. If the level of evidence of a positive effect of a technology is of high or moderate quality it most probably qualifies to be used in routine medical care. If the level of evidence is of low quality the use of the technology may be motivated provided there is an acceptable balance between benefits and risks, cost-effectiveness and ethical considerations. Promising technologies, but a very low quality of evidence, motivate further research but should not be used in everyday routine clinical work.

Christina Bergh, Professor, MD.
Head of HTA-centrum


From operations or activity/management:
Question
Quality assurance process
Main process
Support process
Clinic-based HTA
• Training
• Search, sort, and select process
• Advice, help, assistance
• Feedback
External review
Formally designated group for quality assurance
Summarized assessment
Quality assured decision rationale

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