Improving management of breech presentation at term

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Summary and general discussion
SUMMARY AND GENERAL DISCUSSION

The work presented in this thesis focuses on improvement of care for women with a term foetus in breech presentation in order to improve maternal and neonatal outcome. The results presented in part one emphasise the importance of ECV, as successful versions reduce the rate of planned vaginal breech delivery, and planned as well as emergency caesarean sections with the associated morbidity and mortality for both mother and child. In view of these health benefits associated with ECV, it is important that this intervention is adequately implemented in obstetric practice. The suboptimal implementation of ECV and strategies for improvement are the focus of research in part two and three. First, we have developed implementation strategies based on a determinant analysis to improve the three core elements of the Dutch ECV guidelines: counselling for ECV, advising ECV and arranging an ECV attempt (part two). We then evaluated the effect of these strategies on the implementation of ECV in a cluster randomized controlled trial (part three).

Below, we first summarize the subject and main findings for each chapter. Subsequently we will discuss novel insights, clinical interpretation, and implications for daily practice. We debate on methodological and practical limitations of this work, and in terms of implications and recommendations for further research.

SUMMARY
In chapter 1 we introduced the rationale of this thesis. ECV is the only treatment to prevent breech presentation at birth and thereby the adverse maternal and neonatal outcome during current or subsequent birth. According to the guidelines all women with a breech presentation at 36 weeks gestation and onwards should be offered an ECV attempt, the treatment should be advised and an attempt needs to be arranged after informed consent. However, guidelines are not automatically adhered to in daily practice and improvement of implementation of ECV is needed.

Part one: breech delivery

The first cohort study of this thesis, with data from the Dutch national perinatal registry (chapter 2), showed that publication of the Term Breech Trial resulted in a shift towards elective caesarean delivery up to 60% of
breech birth, within three months of time and remained stable up to 2007. This increase in elective caesarean delivery led to a decrease in perinatal mortality and morbidity among women delivering a child in breech at term. Still, 40% of these women attempt vaginal birth. The relative safety of an elective caesarean should be weighed against the consequences of a scarred uterus in future pregnancies. Presumed risk selection of the women attempting vaginal breech birth since the Term Breech Trial, has not led to better outcome of the planned vaginal deliveries. We were not able to select a subgroup of women based on parity, type of breech, birth weight and onset of labour, with a low risk of adverse neonatal outcome during planned vaginal breech delivery, compared to elective caesarean delivery.

In chapter 3 we describe the consequences of increased elective caesarean delivery rates in nulliparous women with a term breech presentation for future pregnancies. Elective caesarean delivery for term breech presentation leads to a significant increase in maternal morbidity and adverse neonatal outcome in subsequent pregnancies. Combining outcomes of the first and the subsequent pregnancy only resulted in an overall reduction in neonatal morbidity during both pregnancies. Excluding those women with a trial of labour from the analyses, did not alter these findings, accept that the number needed to treat with an elective caesarean delivery to prevent one neonatal morbidity in both (first and subsequent) pregnancies decreased from 95 to 55.

Part two: Development of strategies to improve implementation of ECV

The systematic review of guidelines and literature on contraindications of ECV (chapter 4) showed a lack of consistency. Of the 22 contraindications mentioned in five international guidelines, only one (oligohydramnios) was mentioned in all. Literature does not provide much evidence (not higher than level III) for some of the mentioned contraindications in guidelines. Implementation of ECV is thus hampered by the fact that there is no general consensus on the eligibility for ECV. Therefore, we propose to limit contraindications for ECV to clear empirical evidence or to a clear pathophysiologic relevance.

In chapter 5 we report findings of a vignette study, evaluating women’s preference to opt for ECV regarding different levels of success rates,
experienced pain, use of uterine relaxants and risk of emergency caesarean delivery. Success rates and expected pain are the most important factors influencing the willingness to opt for ECV. These factors need to be addressed during counselling for ECV.

The results of a qualitative analysis of clients’ and professionals’ barriers and facilitators towards ECV are presented in chapter 6. Among professionals the main barriers for ECV were a lack of knowledge and perceived skills to fully inform and counsel clients on ECV, and the experienced difficulty to counsel women who preferred a planned caesarean delivery. The main facilitator was an unambiguous policy on (counselling for) ECV within the region. More time and finance to counsel were also considered to be facilitators. Among pregnant women the main barriers for ECV were fear, incomplete and not well-timed information and incidents of severe birth complications (not necessarily breech related) of significant others. The main facilitator was confidence of the safety of ECV. The preferred mode of delivery could be either a barrier (wish for a planned caesarean delivery) or a facilitator (wish for a planned vaginal birth (at home)).

In chapter 7 we describe the results of the quantitative analysis of the facilitators and barriers for ECV mentioned by the professionals. To do so, we performed an online survey. Professionals’ reported adherence to national guidelines varied from 84% who counselled all women, 73% who always advised ECV, and 82% who succeeded in arranging an ECV attempt for (almost) all their clients. Self-efficacy (degree to which the professional believes he or she is able to implement the activities involved in the guideline) was the most important determinant influencing adherence to national guidelines.

In chapter 8 we describe the outcome of a systematic review of decision aids in pregnancy care. This study was performed to evaluate the effectiveness of a decision aid on informed decision making. We identified ten decision aids, of which one was used to help decide women on ECV. There was a significant increase in knowledge, decrease in decisional conflict and decrease in anxiety among those women who were counselled using a decision aid. The uptake of decision aids in daily practice should be the focus of future studies.
Part three: Evaluating strategies to improve implementation of ECV

In chapter 9 we present the results of a retrospective cohort study on the implementation of ECV in the Netherlands. We evaluated 4,770 breech presentation at birth in 36 hospitals. External cephalic version was performed in 62.2% of the eligible women, with a range from 8% to 84%. Suboptimal implementation was mostly caused by care providers not offering the treatment and by women not opting for ECV. Implementation rates were higher in teaching hospitals, hospitals with special ECV office hours, larger obstetric units and hospitals located in larger cities. An interesting finding was the 7.4% of undiagnosed breech presentations until birth.

Chapter 10 describes the results of our cluster randomised controlled trial in which we evaluated the effect of two implementation strategies on the uptake of ECV. The two implementation strategies, a client strategy (information leaflets and decision aid) and a care provider strategy (one day counselling course focused on knowledge and counselling skills), were developed based on the results described in chapters 6, 7 and 8. The overall implementation rate of external cephalic version in the clusters participating in the cluster randomised controlled trial was 72% (1169 of 1613 eligible clients) with a range between clusters of 8 and 95%. Suboptimal implementation of ECV was mostly caused by the care provider not offering the treatment to eligible women (18.0%) and secondly due to women not opting for the offered attempt (9.5%). We could not demonstrate an effect from either the client nor care provider strategy or the combination of both strategies on the rate of counselled clients, clients opting for ECV and ECV attempts, compared to the care as usual. Adherence to implementation strategies was estimated at 20 to 23%. In per protocol analyses, the overall implementation rates of ECV were higher, but also this analysis did not demonstrate a beneficial effect of any implementation strategy.

The cluster randomised controlled trial revealed important information regarding current practice, i.e. large variety in implementation of ECV among regions. We therefore also performed a cost-effectiveness analysis (chapter 11), in which we compared baseline measurements of the clusters (chapter 9) with their implementation rates after enrolment of the implementation strategies (chapter 10). The results of this analysis indicate that the combined client and care provider strategy can be successful in increasing
ECV implementation rates (mean increase of ECV attempts 7%, range among clusters 3-44%). The incremental cost effectiveness ratio for this strategy was €1,353 to gain one ECV attempt.

In chapter 12 we present the delivery outcomes of all women in our cluster randomised controlled trial. The results confirm the benefits of ECV, with a significantly lower overall caesarean delivery rate in the group of women with an ECV attempt compared to women who did not receive an ECV. Women with a cephalic presentation after ECV had a decreased risk at instrumental vaginal delivery compared to those with a spontaneous cephalic presentation and an increased risk on an overall caesarean delivery compared to women with a spontaneous cephalic presentation.

Chapter 13 describes the effect of our implementation strategies on knowledge and decisional conflict scores in women enrolled in our trial. Baseline knowledge was high and decisional conflict was low. The implementation strategies did not significantly affect these outcomes.
GENERAL DISCUSSION

In this thesis, the suboptimal implementation of ECV in Dutch clinical practice was systematically and thoroughly investigated. We provided a detailed insight in the implementation rates of ECV and quantified the reasons why ECV was suboptimal implemented in a cohort of clusters representative for the Netherlands. We identified barriers and facilitators for ECV on a client and care provider level and developed implementation strategies based on this knowledge. We systematically evaluated these strategies in a cluster randomised controlled trial with a factorial design, due to which we were able to investigate the effects of the single strategies and the combination of both strategies. We measured outcomes to evaluate effectiveness of the strategy as well as care provider adherence to the strategy and finally we also took cost-effectiveness into account. The evaluation of the strategies in the cluster randomised controlled trial did not show a significant effect which might be due to several factors which we will discuss below.

Baseline implementation rates of ECV
What first stood out when the results of our retrospective cohort study (chapter 9) and the cluster randomised trial (chapter 10) became available, was the high overall implementation rate of ECV (72%). However, the variability among clusters was considerable, between 8 and 93%, and one of the most important additional findings of our studies. In advance, no data were available on this overall rate or variation. Based upon implementation rates reported in the literature we estimated the implementation rate to be around 50% in the Netherlands. This resulted in a sample size calculation with an underestimated baseline implementation rate and a relatively optimistic improvement from 50% to 80%. We anticipated to some potential imbalance in baseline implementation rate of ECV among the clusters by stratification on the presence of an ECV office hour as it is plausible that those care providers who have structured care for breech presentation, have better implementation rates than those clusters with a lack of this organized care. However, in randomized controlled trials with a small number of randomized units of observation (25 clusters in our study) even one or two allocated units could cause a considerable imbalance that could also influence the outcomes. The wide range of baseline ECV implementation might be an explanatory factor influencing the lack of significant differences between our implementation
strategies. In a situation with more variability, one needs larger differences in order to demonstrate a statistically significant effect. Re-evaluation of the data in the cost-effectiveness study, taking baseline implementation rates within the clusters into account, did show a potential effect of the combined strategy if clusters were compared to their own baseline measurement.

**Shared decision making on ECV**
During the identification of barriers and facilitators for implementation of ECV, an important issue emerged: the apparent contradiction between pursuing a high uptake of a treatment (as recommended in national guidelines) and shared decision making, meaning counselling of clients by providing unbiased nondirective information on the advantages, disadvantages and expected risks and outcomes of all treatment options and assisting them in clarifying their personal values related to corresponding outcomes and adverse effects. The question is whether a 100% uptake among eligible women needs to be pursued. This might be the best aim regarding improving maternal and neonatal outcome among term breech presentations, and thus from a doctors or even social perspective. However, it does not leave any space for individual women to choose their desired care according to their personal values and believes.

To improve the amount of women opting for ECV, we developed the client strategy based on the results of chapter 6, 7 and 8. The results of our client interviews indicated a lack of well-timed and objective information provision to women with a breech presentation (or at least to a part of them). Therefore we provided timely information presented in an objective information leaflet and decision aid. One could comment that tools like decision aids are developed to stimulate shared decision making, which does not necessarily affect the uptake of a treatment as intended by the guideline. However, it is a proven effective tool to inform clients uniformly and objectively and has a positive effect on informed decision making.

**Effectiveness of implementation strategies**
Due to the set time frame of our study, limited financial resources and manpower, we were restricted in some ways with regard to both the development and a proper introduction of the implementation strategies. Regarding the issue of potential ineffective implementation strategies, some barriers and facilitators could not be incorporated within the implementation strategies. Determinants related to the context or social-political environment
are difficult to change within a short amount of time and/or with limited financial resources. For instance, during the focus group meetings, the lack of a local transparent policy about informing, counselling, referral and performing ECV was frequently mentioned and presence of such a protocol in several clusters was considered to be a facilitator. We were not able to develop such a protocol, let alone influencing the local policy concerning the processes of care, for all participating regions. We have paid attention to this topic during the meetings in the care provider strategy, where we discussed the guideline and the barriers and facilitators for implementation of the guideline. We thereby aimed to improve insight into the care providers’ own clinical practice and uncover those areas where they could improve the provided care. We also presented two examples of well performing ECV office hours in other clusters, as an inspiration source for those clusters without a regional protocol on ECV. However, collaboration between care providers within a cluster is often embedded in a history of organization of care and the attitude of care providers to one another. A more intense way of guidance to improve collaboration within clusters might have been more effective.

Adherence to implementation strategies
Our study and its intention to treat analysis reflects circumstances in daily practice. Just as there is extensive empirical evidence that the level of use of guidelines affects outcomes in clients, this is also true for adherence to implementation strategies. We need to take into account whether a strategy has actually been put into practice by professionals in order to determine its benefits. Otherwise, one may incorrectly conclude that an implementation strategy is not efficacious in itself when, in fact, it has not been properly implemented. There is a lack of publications on implementation strategies with non significant results, potentially indicating a publication bias in favour of those studies with significant results. This might hinder dissemination of knowledge on developed strategies which are effective itself, but which was not shown in the trial due to other influences. Therefore, other research groups cannot benefit from existing knowledge or learn from each other’s mistakes.
Concerning the issue of inadequate adherence, we would like to reflect on two problems. First, inadequate adherence to the implementation strategy is partly caused by the fact that we were only able to organise an introduction session (client strategy) and single one-day course (care provider strategy)
instead of several consecutive ones. This means that some professionals were not able to attend the meeting and were thus not subjected to the implementation strategy, resulting in a potential lower effect of the strategy on implementation of ECV.

Secondly, a systematic introduction of implementation strategies, including feedback on their uptake, takes some time. A similar implementation study has shown that it might take up to two years before optimal effect of the implementation strategy is reached.\(^3\) Ideally, one would first properly introduce the strategies to all care providers, provide for performance feedback, increase their self-confidence as a result of experience in practice and only then measure the results on adherence to the key recommendations in the guidelines.

Within the cluster randomised controlled trial, the majority of eligible clients did not receive an ECV attempt because the care provider did not offer the treatment. Thus, the implementation is mainly limited by the care provider due to suboptimal adherence to existing guidelines, despite the effort to eliminate barriers and to promote facilitators within implementation strategies. Although it is interesting to discuss all practical and methodological issues of our implementation study, at the bottom line the question to all care providers remains why working according to state of the art guidelines is apparently not self-evident. Obviously, every care provider is allowed to deviate from advices in guidelines, if well argued. But this is clearly not the case for ECV as no notification of considering ECV was found in 40% of hospital charts. We have started this thesis with the statement that guidelines are not automatically adhered to by care providers. We would like to emphasize that all care providers are required to adhere to guidelines and to consider this as one of their core clinical tasks in daily practice to provide evidence based care to the clients. The significant difference in ECV implementation rates among clusters indicate that adhere to guidelines in daily practice is conceivable, and poor implementation rates in other regions should not be accepted within current evidence based practice.

### Implications for daily practice

Considering the broad practice variation in the implementation of ECV we recommend that counselling for ECV and ECV attempt outcomes (success rate and complication rates) will be included in national registries (LVR 1 and 2) to enable evaluation of care for term breech presentation in a systematic
way on a yearly basis. This information can be used to provide tailored feedback and guidance to those regions with suboptimal adherence to national guidelines. The effect of these interventions will become clear in following years (and this will complete the circle of Deming (plan-do-check-act) for continuous improvement of health care).

Evaluation of care for breech presentation from these national registries should focus on the proportion of women receiving an ECV attempt as well as the success rate of ECV in order to reach an optimal decrease in breech presentation at birth. We calculated the potential gain to make (optimal implementation and optimisation of ECV success rates) based on the data of our cluster randomised controlled trial and the Dutch perinatal registry 2012 (Figure 1 and 2).

The data presented in this thesis show that around 7% of breech presentation from 36 weeks gestation onwards have a contraindication for ECV according to national guidelines.

The mean rate of women not opting for ECV is 10%. Thus an implementation rate of 83% should be feasible in daily practice, compared to the current 72%. The increase in ECV rate could lead to a decrease of breech presentation at birth from 4,821 to 4,543 per year (5.8%) (Figure 1). (invoegen figuur 1)

Some regions with optimal ECV implementation within our cluster randomised controlled trial achieved success rates up to 60%. These regions did have specialized ECV office hours and their success rates were not biased by case selection (meaning an optimal implementation of ECV rates among eligible women). Achieving such success rates among all ECV attempts can lead to a decrease in breech presentation at birth from 4,821 to 4,543 per year (30.9%) (Figure 2). (invoegen figuur 2) Two potential strategies to increase success rates could either be the implementation of similar ECV office hours in all regions or referral of clients to those regions with the most successful office hours. An third option would be the further evaluation of the use of uterine relaxants during ECV attempts, and the implementation of those uterine relaxants which are proven effective in order to increase ECV success rates.⁴
Chapter 14 Summary and general discussion

**Current implementation of ECV (a) versus optimal implementation (b)**
-5.8% (n=189) planned CS

**Breech presentation (100%)**
- No ECV attempt
  - a. 18% (n=1,859)
  - b. 17% (n=1,128)
- ECV attempt
  - a. 72% (n=4,778)
  - b. 83% (n=5,509)

**Failed ECV (62%)**
- a. n=2,962
- b. n=3,415

**Successful ECV (38%)**
- a. n=1,815
- b. n=2,094

**Breech presentation at birth**
- a. n=4,821
- b. n=4,543
  - n=278 (-5.8%)

**Planned CS (68%)**
- a. n=3,278
- b. n=3,089
  - n=189 (-5.8%)

*The underscored numbers are data from the National perinatal registry 2012 (n=4,821 breech birth, planned CS rate of 68%) and the cluster RCT presented in this thesis (72% ECV attempts and 38% success rate). All other numbers are calculated based on these data.*

**Optimal implementation of ECV (a) versus optimal implementation and high ECV success rates (b)**
-30.9% (n=1,012) planned CS

**Breech presentation (100%)**
- No ECV attempt (17%)
  - n=1,128
- ECV attempt (83%)
  - n=5,509

**Failed ECV**
- a. 62% (n=3,415)
- b. 40% (n=2,204)

**Successful ECV**
- a. 38% (n=2,094)
- b. 60% (n=3,305)

**Breech presentation at birth**
- a. n=4,821
- b. n=3,332
  - n=1,489 (-30.9%)

**Planned CS (68%)**
- a. n=3,278
- b. n=2,266
  - n=1,012 (-30.9%)

*The underscored numbers are data from the National perinatal registry 2012 (n=4,821 breech birth, planned CS rate of 68%) and the cluster RCT presented in this thesis (72% ECV attempts and 38% success rate). All other numbers are calculated based on these data.*
Implications for future research
Although the implementation of ECV may implicate the final step in evidence based care for breech presentation, there are still some issues that remain unanswered.

1. Implementation
With the current research, we gained valuable insight in the implementation of ECV in the Netherlands. Registration of ECV in national databases as a quality indicator will increase this insight. The developed combined client and care provider strategy showed some potential in the cost-effectiveness analysis and therefore could be used within a research setting, to evaluate its potentials in those clusters with poor ECV implementation rates.

2. Effectiveness of ECV
Although the uptake of ECV is an important issue, it remains of importance that once an ECV is attempted, there is a high chance of success. We found that the highest ECV success rates where among regions with an ECV office. Future research should focus on why these practices are so successful. Are these high success rates caused by the skills of the care providers performing ECV, is it the use of uterine relaxants or a combination of these factors?

3. Diagnosing breech presentation
We found that in 3.5% of the term breech deliveries, the breech presentation was only discovered during labour. This is in line with earlier research on detection of breech presentation, in which it is stated that clinical examination is not sensitive enough for detection and timely trimester ultrasound to detect these breech presentations should be performed.
REFERENCES


