Improving management of breech presentation at term

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General introduction
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Three to four percent of term pregnancies are complicated by a breech presentation. Compared to a delivery of a child in the normal cephalic presentation, vaginal breech delivery is associated with increased risk of neonatal birth trauma, low Apgar scores and neonatal death.\textsuperscript{1,2} The advantage of less short-term neonatal morbidity and mortality as a result of an elective caesarean delivery for term breech presentation became clear in the publication of the Term Breech Trial (TBT) in 2000.\textsuperscript{1}

Within three months after publication of this randomised controlled trial (RCT), the elective caesarean delivery rate doubled in the Netherlands up to 60% and remained more or less stable afterwards.\textsuperscript{3,4} Elective caesarean delivery rates in other countries increased even further, up to 90% in the United Kingdom and 96% in Australia.\textsuperscript{5,6} In 2012, 4,822 (3.1\%) of term pregnancies in the Netherlands were in breech presentation, of which 3,258 (68\%) were delivered by elective caesarean.\textsuperscript{3,4} There were a total of 9,811 elective caesarean deliveries for term singletons in the same year. Thus, 33\% of elective caesarean deliveries for term singletons were due to breech presentation.

Although a planned caesarean delivery in case of term breech presentation leads to less short-term neonatal morbidity and mortality as compared to a vaginal breech delivery, there are some relevant clinical points to consider. First, delivery by caesarean section leads to increased maternal and perinatal morbidity in future pregnancies. A systematic review of Guise et al.\textsuperscript{7} concluded that the rate of uterine rupture for all women with a prior caesarean delivery is 30 per 10,000. This risk was significantly increased with a trial of labour (47 per 10,000 versus 3 per 10,000 elective repeat caesarean delivery). Six percent of uterine ruptures were associated with perinatal death. Perinatal mortality was significantly increased for a trial of labour at 13 per 10,000 deliveries versus 5 per 10,000 for elective repeated caesarean delivery. Furthermore, in the Netherlands four maternal deaths occurred between 2000 and 2002 after elective caesarean delivery for breech presentation.\textsuperscript{8}

External cephalic version (ECV) is an obstetrical intervention that has been proven to reduce the number of breech presentations. It can increase the rate of cephalic presentation at birth by 40\% and consequently reduce the caesarean delivery rate.\textsuperscript{9} ECV is also a relative safe intervention. A meta-
analysis reporting on 12,955 ECV attempts showed a pooled complication rate of 6.1% (95% CI 4.7 to 7.8%), 0.24% for serious complications (95% CI 0.17 to 0.34%) and 0.35% for emergency caesarean deliveries (95% CI 0.26 to 0.47%).

The history of external cephalic version: from Hippocrates towards evidence based guidelines

Breech presentation and manoeuvres to turn a foetus in the womb have been known since ancient times. Hippocrates was one of the first men reporting on breech presentation. The scripts of Hippocrates and later on, the book of Rösslin showed awareness about perinatal risks for mother and foetus, but they could not react on it as they had limited knowledge about the pathophysiology of breech presentation and the process of a vaginal breech delivery. Hippocrates described in his scripts (460-377 BC) a breech delivery as extremely difficult. Hippocrates thought that normal birth could only take place if the foetus was able to push its way out by putting his feet to the fundus uteri, of which a foetus in breech position was incapable to do so. If birth in breech presentation did not progress, they tried to turn the foetus around as they thought that the foetus needed his feet to push to the fundus uteri. In those days it was attempted by shaking the woman ten times during labour and putting her bed into the Trendelenburg position. If these movements did not result in a vaginal birth, Hippocrates advised to clasp the foetus and to turn the head through the birth canal, making a vaginal birth possible. If this treatment did also not succeed or if the birth attendant was convinced that a vaginal birth was not possible, Hippocrates advised an embryotomy (mutilation of a foetus to facilitate removal from the womb when natural delivery is impossible). Till medieval times, the scripts of Hippocrates were the most important documents of obstetric care. Thereafter, knowledge of Hippocrates was adopted by the Arabs and transferred to Western Europe in Islamic writings.

Eucharius Rösslin, a German physician, wrote in 1513 a book about childbirth (‘Der Rosengarten’) what became a manual for midwives. Rösslin described the possibility to turn a foetus by internal handholds to a cephalic presentation during labour and in case of no success to move the arms towards the legs and to extract the foetus. He described that breech presentation could be associated with prolonged labour and a prolonged or failed second stage of labour.
During the Renaissance the knowledge of the anatomy of the human body increased (Vesalius 1514-1654 and Fallopius 1523-1562). Vesalius was a Dutch pathologist-anatomist who wrote the “Humani Corporis Fabrica Libri septem” in which he described the human anatomy. Gabriele Falloppio is nowadays well known from the Fallopian tubes, the two very fine tubes between the ovaries and the uterus. He was born in Italy and was one of the most important anatomists of the sixteenth century. He studied the reproductive organs of the human bodies, which provided more insight in the process of vaginal births. Despite of this knowledge, breech delivery remained full of perinatal risks for mother and child and turning a foetus in breech position to cephalic position, was not often applied.

In the 18th century physicians became more involved in the actual process of childbirth leading to a change in obstetric care. Bringing in their knowledge of the human anatomy modernised obstetric care. It took till the 19th century that more attention was paid to the safety of vaginal breech birth and the possibility of external cephalic version (ECV).

Professor Adolphe Pinard (1844-1934), a French obstetrician, is seen as the founder of abdominal palpation. In 1878 he advised to examine every woman before birth to detect abnormal foetal presentations. He also recommended to turn a foetus, presenting in transverse presentation to cephalic presentation which was not done or opted before.

In the same time obstetricians (Wigand, 1820; De Snoo 1910) started to publish about manoeuvres for an assisted vaginal breech delivery. Wigand, a German obstetrician described in his book “Die Geburt des Menschen” (1820) a manoeuvre for an assisted breech delivery, known as the Wigand manoeuvre, which made the development of the foetal head safer. De Snoo also described a manoeuvre to develop the foetal head after breech presentation to prevent the foetus for adverse perinatal outcomes.

The first publications on ECV appeared in 1928 by McGuinness. McGuinness was a lecturer in obstetrics at the University of Manitoba (Winnipeg). In 1927 he gave a lecture for the Winnipeg Medical Society in which he presented the results of breech births and external cephalic version attempts in his clinic of the University of Manitoba. Based on the adverse outcomes of breech births in his clinic, he decided to apply ECV to all his patients with breech presentations. Of the 62 presentations, 57 had a successful ECV at-
tempt. Three times a contraindication for ECV (twice a multiple pregnancy and once premature labour) was present and two ECV attempts failed. In one case an emergency caesarean delivery was necessary and in one case fetal death occurred after a partial placental abruption during labour. It is not clear if labour started short after ECV. In the same paper he wrote about the technique of ECV and the timing of an ECV attempt. He concluded that while waiting for a spontaneous version the most favourable time for ECV could be lost.

Later on, around the years 1950 and beyond, more publications on ECV and the mode of delivery of breech presentations appeared. It was already in that time that obstetricians discussed about unfavourable conditions for ECV such as oligohydramnion, multiple pregnancies, parity and ruptured membranes.\textsuperscript{13,14}

At the same time ECV was subject of discussion in the Netherlands. In a publication of the Dutch Journal of Medicine in 1940, the safety of ECV was discussed by Van der Hoeven, Treub and Kouwer.\textsuperscript{13} They had opposing opinions regarding ECV; they feared wrong diagnosis, severe complications like placental abruption and they disagreed on the chances of success. ECV fell into oblivion and it took many years before it became routine practice again. In 1980, two Dutch obstetricians (Mensink and Huisjes) stated that ECV was not useful at 33 weeks gestations and discussed whether it was after 33 weeks gestation.\textsuperscript{15} In 1987, following international publications that showed that ECV could be useful in modern obstetric care obstetricians, the Dutch obstetricians van Raaij and Van der Lugt reopened the discussion concerning the application of ECV.\textsuperscript{16} They reviewed international publications of 1980 onwards and formed, based on this review, a list of absolute contraindications for ECV: multiple pregnancies, placenta praevia or low insertion of the placenta, scarred uterus, fetal anomalies, intra uterine growth retardation, necessity for a planned caesarean, ruptured membranes, toxicosis, hypertension, foetal distress, and antepartum bleeding in history. Obesity, oligohydramnion and anterior placenta were mentioned as relative contraindications. They also described the prerequisites for a safe ECV attempt. They concluded that ECV was an important intervention in modern obstetric care and should be routine practice.\textsuperscript{16}
Current practice: the implementation of ECV

After publication of the results of the Term Breech Trial in 2000, the professional organizations of obstetric care in the Netherlands (NVOG and KNOV) published guidelines in which they recommended to advise and to offer ECV to all women with a in foetus in breech presentation from 36 weeks onwards. Guidelines have in common that they recommend a treatment based on evidence but also mention contraindications for the treatment. Guidelines can differ in the definition of contraindications. Contraindications for ECV mentioned by both guidelines are: oligohydramnion and a history of placental abruption. The NVOG also mentions ruptured membranes and uterine anomaly as contraindications. The KNOV adds multiple pregnancies, severe intra uterine growth retardation, severe hypertension, placenta praevia, third trimester bleeding (unknown cause), scarred uterus as contraindications to it. Both guidelines advise a similar routine: to use ultrasound to ascertain foetal position before and after an ECV attempt, to monitor foetal condition before and after the attempt, and to administer anti-rhesus immunoglobulins in case of a rhesus negative blood of the mother and rhesus positive blood of the foetus. The NVOG advises to perform ECV within a hospital setting, the KNOV describes the possibility to perform ECV in midwives’ practices (out of hospital setting). The KNOV guideline also addresses to the training of midwives on ECV. Only ECV certified midwives who are registered are allowed to perform ECV. Those midwives followed a training on ECV and have to meet several quality requirements yearly in order to keep their competence. All ECV attempts by midwives are registered by the KNOV in a national database. Data are not published yet. Advice on required professional skills and quality control is lacking in the guideline of the NVOG.

Although the guidelines are quite clear in their advice to counsel for ECV and arrange possibilities for ECV, the ECV uptake by both health care professionals and patients shows wide variation. An inventory survey among all hospitals in the Netherlands in 2007 reported that 5% of the gynaecologic practices did not perform ECV at all. In the United Kingdom and Australia the number of eligible women who were not offered an ECV attempt ranged from 4% to 33%. and external cephalic version (ECV An Australian preference study showed that 39% of women did not opt for ECV and a similar study in Israel reported a decrease in women willing to undergo ECV from 54% to 24%. Based on these figures, we estimated the implementation
rate of ECV (defined as the amount of patients having an ECV attempt of all breech presentations after 36 weeks gestation) in the Netherlands overall to be around 50 to 60, which we consider too low and important to increase. As there is sound evidence supporting an ECV in case of a term breech presentation, it is clear that there is room for improvement of the implementation of ECV.

**Improvement of implementation of the guidelines**

Despite of the fact that both professional organizations responsible for obstetrical care updated their guidelines in 2008 and brought the update to the attention of their members, the number of breech presentations at birth remained stable over the years.

Implementation of clinical practice guidelines is a common problem in the health care system; new or revised guidelines are not automatically used by professionals. Several models and frameworks have been developed to improve the uptake of guidelines by paying attention to a systematic introduction within the existing health care system. They all emphasise the importance of a detailed understanding of critical factors, or so-called determinants, that may enhance or impede the use of guidelines. Analysis of determinants before, or even after the introduction of a guideline, can guide the process of designing innovation strategies that will have the potential to create real change in the actual use of the guideline by health care professionals.

In 2008 a grant was obtained for a research project to address the suboptimal implementation of ECV in the Netherlands. The project encompassed investigation of determinants of poor implementation (determinant analysis), the development of strategies to improve the implementation of ECV in the Netherlands, and evaluation of the (cost)effectiveness of these strategies. In our project, we used a framework based on several theories that have been used for the introduction and evaluation of innovations in a wide range of domains in (Dutch) health care. An implementation process is divided in four main consecutive stages: dissemination (meaning that every professional is actually supplied with the guideline); adoption (the intention of the professional to use or not to use the guideline); implementation (the use of the guideline in daily practice); and continuation (working with the guideline becomes routine practice). Several determinants may positively or
negatively influence the transition from one stage to the other and can be divided in four main categories: 1. Characteristics of the guidelines (e.g. procedural clarity, complexity), 2. Characteristics of the health professional (e.g. personal benefits/drawbacks, outcome expectations, self-efficacy, client/patient cooperation), 3. Characteristics of the organisation (e.g. staff capacity, financial resources, available time), and 4. Characteristics of the socio-political environment (e.g. legislation and regulations). Thus, knowledge of the critical determinants facilitates the development of implementation strategies with the potential to actually improve the implementation of a guideline. These insights are applied in our project.

**AIM OF THIS THESIS**

The central aim of this thesis was to evaluate current care for term breech presentation. We have studied the following questions:

1. What is the effect of the increased elective caesarean delivery rates for term breech presentation on maternal and neonatal outcome, and is there still room for improvement left?

2. What is the effect of an elective caesarean sections for breech presentation on maternal and neonatal outcome in the subsequent pregnancy?

3. Which determinants hamper or facilitate the implementation of the guideline on ECV in the Netherlands?

4. What is the effectiveness of a client strategy, a care provider strategy or a combination strategy for the implementation of the guideline on ECV, in terms of:

   a. adherence to the three core elements of the ECV guidelines: counselling for ECV, advising ECV and arranging an ECV attempt.

   b. mode of delivery and maternal and neonatal outcome

5. What are the costs of the implementation strategies and how do they relate to their effectiveness?
OUTLINE OF THE THESIS

In part one of this thesis, we will address the change in mode of delivery for breech presentation at term since publication of the Term Breech Trial and its effect on perinatal and maternal outcome.

Chapter 2 describes the trend in mode of delivery for term breech presentations between 1999 and 2007 and the effect on perinatal outcome of the increased planned caesarean section rate since publication of the Term Breech Trial.

Chapter 3 describes the effect of the increased caesarean section rate due to breech presentation on maternal and perinatal outcome in the subsequent pregnancy.

In part two of this thesis, we identify which issues are potentially related to suboptimal implementation of ECV:

In chapter 4 we systematically reviewed the literature to assess whether the formulation of contraindications in guidelines is based on empiric data.

Chapter 5 evaluates patients’ willingness to opt for EV by means of a vignette study.

Chapter 6 describes a qualitative analysis of patients’ and professionals’ determinants (barriers and facilitators) for ECV, identified by patient interviews and focus group meetings with professionals.

Chapter 7 describes an online survey to evaluate the extent to which the barriers and facilitators for professionals influence the ability to counsel, advice and arrange an ECV. This was done by means of a quantitative analyses of an online questionnaire on the identified determinants.

Chapter 8 presents a systematic review on the potential of decision aids in obstetrics to improve informed decision making.

In part three, we describe and evaluate the implementation strategies we developed, based on the information obtained in part two.

Chapter 9 presents a retrospective description of the implementation rate of ECV from January 1st 2008 till December 31st 2009 in the participating
clusters in the randomised controlled trial.

Chapter 10 presents the results of the cluster randomised controlled trial on implementation strategies for ECV in 25 clusters in the Netherlands.

Chapter 11 evaluates the cost-effectiveness of the implementation strategies.

Chapter 12 describes the effect of the implementation strategies for ECV on the decisional conflict patients experience when deciding on ECV.

Chapter 13 describes the effect of ECV on mode of delivery in comparison to patients who do not opt or to whom ECV is not offered.

In the addendum of the thesis the study protocol is presented.
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