## Term breech delivery in The Netherlands

Rietberg, Christine
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### Term breech delivery in The Netherlands

## A terme stuitligging in Nederland

(met een samenvatting in het Nederlands)

#### Proefschrift

Ter verkrijging van de graad van doctor aan de Universiteit Utrecht op gezag van de Rector Magnificus, Professor dr W.H. Gispen, ingevolge het besluit van het College voor Promoties in het openbaar te verdedigen op dinsdag 31 oktober 2006 des middags te 4.15 uur door

Christine Cornelie Theodora Rietberg

geboren op 16 december 1965 te Dordrecht

Promotor: Professor dr G.H.A. Visser

Copromotor: Dr P.M. Elferink-Stinkens (Erasmus Medisch Centrum)

Voor Oscar Leonie, Cecile en Claire

### TABLE OF CONTENTS

List of	abbreviations	and exp	olanations

Chapter 1	1
Introduction, aim and outline of this thesis	
Chapter 2 Term Breech presentation in The Netherlands from 1995 - 1999: mortality and morbidity in relation to the mode of delivery of 33,824 neonates BJOG June 2003, vol. 110: 604 – 609	11
Chapter 3 The effect of the Term Breech Trial on medical intervention behaviour and neonatal outcome in The Netherlands: an analysis of 35,453 term breech infants BJOG feb 2005; vol. 112: 205 – 209	25
Chapter 4 Increased neonatal morbidity and mortality after vaginal trial of labor: a study in 11,080 term breeches Submitted for publication	37
Chapter 5 Why did the Term Breech Trial have such strong influence? A survey among 100 obstetric departments	51
Chapter 6 There are more girls than boys in breech position Submitted for publication	71
Chapter 7 Congenital malformations among infants in breech position: a study of 1.4 million newborns Submitted for publication	81

Chapter 8	95
Summary and general discussion	
Chapter 9	119
Nederlandstalige samenvatting	
List of co-authors	131
Dankwoord	133
Curriculum Vitae	137
List of publications	139



#### LIST OF ABBREVIATIONS AND EXPLANATIONS

AS Apgar score

CBS centraal bureau voor de statistiek = central statistics office

CI confidence interval

CNS central nervous system

CS caesarean section
DES diethylstilbestrol

EBM evidence based medicine
ECV external cephalic version

EPH emergency peripartum hysterectomy
HIE hypoxic-ischemic encephalopathy

HIE hypoxic-ischemic encephalopathy

IRDS idiopatic respiratory distress syndrome

LNR landelijke neonatale registratie = national neonatal database

LVR landelijke verloskunde registratie = national obstetric database

*n* number

NTD neural tube defect

NVOG Nederlandse vereniging voor obstetrie en gynaecologie =

Dutch society of obstetrics and gynaecology

OR odds ratio

pCS(%) planned caesarean section (percentage)

Planned CS (breech) planned CS for breech position only

Planned CS (other) planned CS for reasons other than the fetal position

PMR perinatal mortality rate

PRN perinatale registratie Nederland = Netherlands perinatal

registry

Q question

RCT randomised controlled trial

RR relative risk

TBT term breech trial

(V)TOL (vaginal) trial of labour

The punctuation mark '–' in between measures, such as years or weeks of gestation, indicates that the year or week following the mark is included. For weeks of gestation this implies the following: '37 – 41' means 37  $^{0}$ /<sub>7</sub> weeks up to and including 41  $^{6}$ /<sub>7</sub> weeks.



Introduction, aim and outline of this thesis

#### INTRODUCTION

In developed countries (USA, England/Wales, Northwest European countries) maternal mortality has stayed high until the mid-1930's, when a steep decline occurred as a result of the introduction of sulfonamides and antibiotics and improved obstetric care, including safer operations and possibilities for blood transfusion. Maternal mortality fell from 250-700 per 100,000 births before 1925 to less than 100 per 100,000 births around 1950 (and to 10 per 100,000 at present).<sup>1</sup>

Also infant mortality declined dramatically from 120-220 deaths per 1000 births around 1900 to 29-40 deaths per 1000 births in the 1950's (and around 3 per 1000 at present). Following this decline in maternal and infant mortality, a favourable perinatal outcome became increasingly important. Attention to high-risk deliveries such as breech presentations became more and more relevant. Around 1950 several studies appeared, advocating that external cephalic version in case of breech would be beneficial and that a caesarean section (CS) on the fetus in breech presentation would reduce perinatal risks of mortality and morbidity. Since then obstetric policies in general and in relation to breech presentation in particular have gradually changed towards more interventions and a less conservative attitude. This has resulted in an increase of CS's over the years. In The Netherlands the overall percentage of CS increased from 5.2% in 1983 to 14% at present.

Around 2000 the percentage of CS for term breech in The Netherlands had gradually risen to approximately 50%. About 20% were planned elective CS's and the other 30% were emergency CS's or CS's because of other pathology.

Until 2000, only a few small randomised trials had been published on outcome in case of term breech presentation. In 1980 Collea *et al.*<sup>12</sup> analysed 208 women with a singleton term fetus in frank breech. Of those, 115 women were randomised to a trial of labour (TOL), but almost half of these had to be excluded because of the results of X-ray pelvimetry. Of the remaining 60, 49 (82%) delivered vaginally without perinatal deaths, but 2 infants had a persistent brachial plexus palsy. No maternal deaths occurred among the 148 women who delivered by CS, but 49% experienced post partum morbidity (as compared to 7% of women after vaginal delivery).

In 1983 another study from the same institute was published by Gimovsky *et al.*,<sup>13</sup> reporting on the results of 105 women with a term singleton fetus in non-frank breech position. Seventy (67%) were randomised to a trial of labour and 35 (33%) to elective CS. Of the 70 women allocated to TOL, 23 had inadequate X-ray pelvimetry and underwent CS. Of the remaining 47 women, vaginal TOL was successful in 31 (70%). There was

Introduction 3

#### MEDIAEVAL MYTHS AND CAUSES OF BREECH POSITION

Customs and myths concerning pregnancy are as old as mankind. When focussing on mediaeval customs, one notices that many were actually not so strange, but contained an important underlying meaning. They were passed down from generation to generation. Apart from religious influences big fears were often hidden behind the – usually most friendly – customs. Especially after the mediaeval period many people feared evil spirits and witches. These are a few of the many myths that can be found:

- The expectant mother should not have a tooth extracted, otherwise she would have a risk of miscarriage.
- She should not drink milk, lest the baby would be too heavy.
- She should not walk underneath a rope: the baby would be strangled by the umbilical cord.
- She should not see a dead person, otherwise her baby would die.
- She should not raise her hands above her head, otherwise the baby would turn in breech position.
- She should not put her hands in cold water, lest she would get chilled and the baby would drink all of its mothers fluids.
- She should not open the linen closet, for this would cause the baby to have seizures.

In light of the risks for the pregnant woman and her child in those days – when preventive and prenatal care hardly existed – these fears are actually quite understandable. From the myth about raising the hands one can conclude that the increased risk associated with a vaginal birth of a baby in breech was well understood.

Intermezzo

one neonatal death after vaginal delivery, probably caused by inadequate resuscitation. Two neonatal deaths occurred in infants with major congenital malformations. Neonatal morbidity was equal for those delivered vaginally or by CS. Maternal morbidity was significantly greater among women who delivered by CS.

Many retrospective studies on outcome in case of term breech presentation were published in the years before 2000. Most compare vaginal breech delivery with caesarean section without differentiating between a planned elective or an emergency caesarean section. The conclusions vary considerably. Several studies conclude that in selected cases of breech presentation vaginal delivery is just as safe for the infant as a delivery by planned caesarean section. Others seriously advocate a planned caesarean section as the safest mode of delivery for the term fetus in breech position. Two meta-analyses were published, one by Cheng and Hannah in 1993 and one by Gifford *et al.* In 1995. Both meta-analyses concluded that vaginal delivery of the term breech infant is associated with a higher risk of perinatal mortality and morbidity.

#### THE TERM BREECH TRIAL AND ITS EFFECTS

In 2000 a drastic change in policy concerning term breech occurred, all as a result of one randomised trial: the Term Breech Trial (TBT),<sup>42</sup> carried out by the Term Breech Trial Collaborative Group. In this large international multi-centre trial 2083 women from 121 centres in 26 countries were randomised after careful selection (only frank or complete breech presentation; no evidence of feto-pelvic disproportion). The analyses were carried out according to the 'intention-to-treat' principle. Of the 1041 women assigned for planned CS, 941 (90.4%) delivered by CS. Of the 1042 women assigned for planned vaginal delivery, 591 (56.7%) delivered vaginally. Five babies with lethal congenital malformations were excluded from the analysis.

Table 1. Results from the Term Breech Trial. PMR=perinatal mortality rate.

	Planned CS	Planned vaginal delivery	RR	95% confidence interval
n	1039	1039		
CS	941 (90.4%)	551 (43.3%)		
Perinatal mortality	3 (0.3%)	13 (1.3%)	0.23	0.07 – 0.81
<ul> <li>low national PMR</li> </ul>	0 / 514	3 / 511 (0.6%)	-	-
<ul> <li>high national PMR</li> </ul>	3 / 525 (0.6%)	10 / 528 (1.9%)	0.30	0.08 - 1.09
Serious neonatal morbidity	14 (1.4%)	39 (3.8%)	0.36	0.19 – 0.65
<ul> <li>low national PMR</li> </ul>	2 / 514 (0.4%)	26 / 508 (5.1%)	0.08	0.02 - 0.32
<ul> <li>high national PMR</li> </ul>	12 / 522 (2.3%)	13 / 518 (2.5%)	0.92	0.42 - 1.99
Combined mortality/morbidity	17 (1.6%)	52 (5.0%)	0.33	0.19 – 0.56
<ul> <li>low national PMR</li> </ul>	2 / 514 (0.4%)	29 / 511 (5.7%)	0.07	0.02 - 0.29
<ul> <li>high national PMR</li> </ul>	15 / 525 (2.3%)	23 / 528 (4.4%)	0.66	0.35 - 1.24

The results showed a perinatal mortality of 1.3% after planned vaginal delivery and 0.3% after planned CS. The risk of perinatal mortality or serious morbidity together was 5.0% and 1.6%, respectively (Table 1). It was concluded that planned CS is better for the term fetus in breech presentation and that serious maternal complications were similar between the groups.

The effects of this trial in The Netherlands were remarkable (Figure 1). Within 2 months following publication the total CS rate for term breeches increased from 50% to 80%, all

Introduction 5

as a direct result of an increase of the planned elective CS, which rose from 20% to 50%. In other countries there was also an increase in CS rate, but less distinct. This may be due to the fact that in those countries the CS rate in case of a breech presentation had been higher anyway.

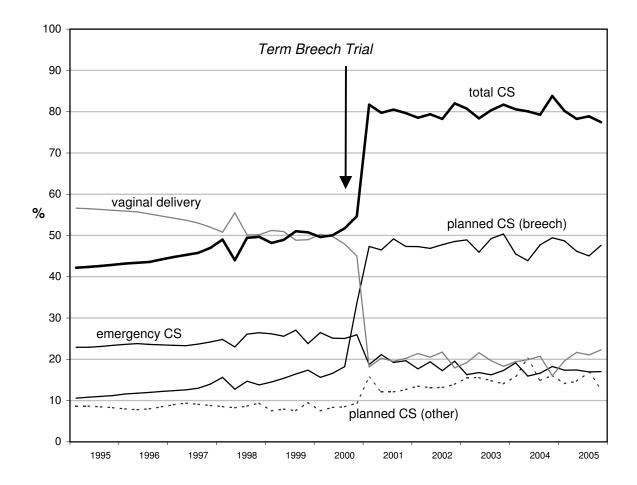


Figure 1. Percentage intervention for term breech presentation over 10 years.

Such a sudden and remarkable change in clinical practice does not occur often. It is a well known fact that adopting new insights and procedures in medical practice usually takes years, or takes place incompletely or not at all. A notorious example of delayed implementation of new insights is the prolonged prescription of the hormone diethylstilbestrol (DES).

DES was first prescribed by physicians in 1938 to prevent miscarriages or premature deliveries. It was considered effective and safe for both the pregnant woman and the developing baby. A double-blinded study was not done until DES had been on the market for more than a decade (1953).<sup>43</sup> Even though there were no positive effects of DES

found, it continued to be aggressively marketed and routinely prescribed until 1971, when it was linked to a rare vaginal cancer in female offspring.<sup>44-46</sup> Nevertheless, in many countries DES continued to be prescribed after 1971 (until 1978 in most European countries and even as late as 1994 in some third world countries).

The results of the Term Breech Trial and the fast increase in CS rate in The Netherlands stimulated the research that has led to this thesis. Soon after the publication of the Term Breech Trial many questions arose among obstetricians, leading to animated discussions about whether this trial was applicable to the Dutch situation. In The Netherlands thus far there had been a selective and conservative approach concerning the term breech presentation, resulting in a rather high percentage of vaginal deliveries and therefore broad expertise in this field.

The rapid change in policy formed a unique opportunity to evaluate if this change has resulted in a better perinatal outcome among term breech infants.

#### AIM AND OUTLINE OF THIS THESIS

This thesis aims to answer the following questions concerning the term breech presentation:

- 1. What was the perinatal mortality and morbidity rate in The Netherlands before the Term Breech Trial, with respect to the different modes of delivery?
- 2. What was the effect of the TBT on medical intervention behaviour and neonatal outcome in The Netherlands?
- 3. What is with the new policy the risk of perinatal mortality and morbidity in case of vaginal trial of labour and in case of planned elective caesarean section?

Furthermore, we investigated whether gender differences play a role in breech presentation. In the past there have been indications that a female preponderance is present among infants in breech position.<sup>47-50</sup>

In the analyses on perinatal mortality and morbidity infants with congenital malformations were excluded. Since there are indications that congenital malformations are more frequently present in infants born in breech presentation, <sup>49,51-53</sup> we have studied this separately, comparing it with fetal cephalic presentation, taking into account possible gender differences.

To address these questions we conducted several studies, of which the results are presented here.

Introduction 7

In **chapter 2** an analysis of the five-year period prior to the Term Breech Trial, using data from the Dutch Obstetric Registry (LVR-2), is described. Mode of delivery was divided into planned caesarean section for breech or for other pathology, emergency caesarean section and vaginal delivery. Perinatal mortality and perinatal morbidity - defined as low 5-minute Apgar score and trauma - were analysed in relation to the mode of delivery.

**Chapter 3** focuses on the effect of the Term Breech Trial on medical intervention behaviour among Dutch obstetricians. Perinatal mortality, low Apgar scores and trauma during a 33-months period before the Trial and the first 25-months thereafter were compared.

**Chapter 4** describes the analyses of perinatal mortality and morbidity among term breech infants in the years 2001-2003, using a comprehensive perinatal database, with a combination of obstetric data collected by the obstetricians and neonatal data from the paediatricians. With this linked data perinatal outcome, especially severe neonatal morbidity, could be analysed more extensively and more precisely.

In **chapter 5** the results of a survey questionnaire among all Dutch obstetric departments are presented. The aim of the questionnaire was to understand the factors that caused the rapid and dramatic increase in CS rate among term breech births.

In **chapter 6** gender differences among infants in breech position are presented as well as the prevalence of breech position as a function of gestational age (between 24 and 42 weeks).

In **chapter 7** we analysed a large cohort of 1.4 million newborns, with more than 70,000 in breech position. A linked perinatal registry of obstetric and neonatal caregivers was the basis for this study. The prevalence of 70 different congenital malformations was analysed. We compared breech with vertex and male with female infants.

In chapter 8 our findings are summarised and discussed.

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Introduction 9

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## 2

Term breech presentation in The Netherlands from 1995 - 1999: mortality and morbidity in relation to the mode of delivery of 33,824 neonates

Christine C.Th. Rietberg
Patty M. Elferink-Stinkens
Ronald Brand
Aren J. van Loon
Oscar J.S. Van Hemel
Gerard H.A. Visser

#### **ABSTRACT**

**Objective:** To analyse neonatal mortality and morbidity in term infants born in breech presentation in relation to the mode of delivery (planned caesarean section, emergency caesarean section or vaginal delivery) and to compare these findings with those of the Term Breech Trial Collaborative Group (Hannah *et al.*; Lancet Oct 2000).

**Design:** Retrospective observational study.

**Setting:** The Netherlands.

**Population:** Infants (*n*=33,824) born at term in breech presentation in The Netherlands between 1995 - 1999. Multiple pregnancies, antenatal death and major congenital malformations were excluded.

**Methods:** Data derived from the Dutch Perinatal Database was used to compare neonatal outcome of infants born in breech presentation in relation to the different modes of delivery, i.e. planned caesarean section, emergency caesarean section and vaginal delivery. Corrections were made for differences in parity, duration of gestation and birth weight, using logistic regression.

Main Outcome Measures: Intrapartum and first-week neonatal death, 5-minute Apgar score and birth trauma.

**Results:** Vaginal delivery and emergency caesarean section resulted in a seven-fold increase in low Apgar score, a three-fold increase in birth trauma and a two-fold increase in perinatal mortality, when compared with the results of planned caesarean section.

**Conclusions:** This study confirms the data found by Hannah *et al.* on an increase in early neonatal morbidity and mortality, following a trial of labour in cases of term breech presentation. This data requires carefully weighed consideration against increased maternal (long term) risks due to a rise in caesarean sections.

#### INTRODUCTION

In The Netherlands, vaginal delivery in case of breech presentation was a common practice until the publication of Hannah *et al.*<sup>1</sup> in the Lancet, October 2000. Roughly 25% of all term breeches were delivered by planned caesarean section (CS), 25% by CS during trial of labour (emergency CS) and 50% were delivered vaginally. There were guidelines offered by the Dutch Society of Obstetrics and Gynaecology,<sup>2</sup> and the general opinion was that a vaginal delivery in a term breech was safe in a well-selected population.

The Netherlands retain a nation-wide perinatal database, including ca. 100% of all hospital deliveries.<sup>3</sup> Breech deliveries are only carried out in hospitals and therefore this database provides a powerful instrument for outcome studies on breech presentation and delivery, given the large amount of data it contains. This large cohort may overcome some of the drawbacks associated with an observational and retrospective design.

This chapter addresses differences in direct neonatal outcome of infants born in breech presentation who were delivered by planned CS (because of breech position or due to other reasons), by vaginal delivery or by emergency CS after a trial of labour.

#### **METHODS**

The Dutch Perinatal Database includes 50 obstetric items relating to pregnancy, delivery and neonate.<sup>3</sup> This database was initiated in 1982 for hospital deliveries, and in 1985 for deliveries attended by first-line care givers (predominantly midwives). This study analysed the hospital perinatal database of the years 1995-1999. The inclusion criterion was breech presentation and delivery at term, i.e. between 37 - 41 weeks of gestation. Hannah *et al.* only included neonates with an estimated birth weight of ≤ 4000g. Although we were not in a position to directly compare our method of analysis with that of Hannah *et al.*, because they used prenatal estimated birth weight, whereas we used actual postnatal birth weight, for comparative reasons, we initially restricted our analysis to the same weight category and later performed a second analysis on infants weighing > 4000g. Exclusion criteria were multiple pregnancy, antenatal fetal death and major congenital malformations (central nervous system abnormalities, such as spina bifida, meningomyelocele, exencephaly, anencephaly, hydrocephaly and microcephaly and infants with multiple congenital malformations, including intestinal atresias and congenital

heart disease). In total, 31,439 neonates with birth weights  $\leq$  4000g were included and 2385 infants with weights > 4000g.

A sub-analysis was performed on gender, in order to investigate whether outcome among boys and girls was different. (This sub-analysis was not included in the original article).

Since outcome might be related to induction or augmentation of labour, a sub-analysis was performed on 16,884 deliveries before 41 weeks of gestation, and in which no oxytocic drugs were used.

To investigate whether different local policies affect outcome, all 119 hospitals were subdivided according to their overall planned CS rate for breech presentation (0 - 17%; 17% - 26%; > 26%).

Complications with the after-coming head as reported as such in the registration, sometimes necessitating assisted delivery by forceps (an uncommon procedure in The Netherlands), were also analysed, in relation to the duration of the second stage of labour and to neonatal morbidity and mortality.

The indications for planned CS, i.e. with no intended trial of labour, are subdivided in the perinatal database in 'elective', 'condition of the mother', 'condition of the fetus', 'condition of the mother and fetus' or 'unknown'. In this way, specific fetal problems (such as fetal growth retardation or signs of antenatal asphyxia) are coded separately, leaving the category 'elective' for planned CS due to breech presentation only, without additional pathology. For this study, we subdivided planned CS into:

- 1. Planned CS because of breech position (planned CS [breech]); and
- 2. Planned CS for other reasons than the existing breech position (planned CS [other reasons]).

Perinatal mortality was defined as intrapartum death or death within a week following birth. The 5-minute Apgar scores were subdivided in scores kleiner dan 7 and  $\geq$  7, according to recent reports from Sweden and Norway on prediction of long-term neonatal morbidity.<sup>4,5</sup>

Neonatal trauma was classified as intracerebral haemorrhage, cephalic haematoma, facial nerve palsy, brachial plexus lesion, fracture of clavicle, humerus or femur and other trauma.

In 0.7% of cases, the mode of delivery was not coded, and these cases are mentioned separately in Tables 1 and 2.

Odds ratios on mortality, low AS and trauma were calculated for planned CS (breech) as compared to emergency CS or vaginal delivery and for the total planned CS group (for breech or other reasons) as compared to emergency CS or vaginal delivery. Logistic regression was used to calculate the adjusted odds ratios for the different modes of delivery, correcting for parity, birth weight and gestation.

#### **RESULTS**

The median percentage of breech presentations at term in the total hospital population was 8.2%, with a variation among hospitals of 4.2% - 12.4%. The mean percentage of overall planned CS in cases of breech position was 21.8% for infants with a birth weight ≤ 4000g. The mean percentage of emergency CS was 24.3%, resulting in a total CS percentage of 46.3% (Table 1). Between 1995 and 1999 there was a rise in planned CS and, to a lesser extent, emergency CS. Overall, 61% of all planned CS were coded as planned due to breech presentation.

Table 1. National Dutch data on mode of delivery among singleton term neonates in breech position, with a birth weight ≤ 4000g, from 1995 – 1999. Annual percentages in brackets.

	Planned CS (breech)	Planned CS (other reasons)	Emergency CS	Vaginal delivery	Unknown mode of delivery	Total
1995	619 (10.8)	499 (8.7)	1317 (22.9)	3243 (56.5)	62 (1.1)	5740
1996	696 (11.8)	461 (7.8)	1403 (23.8)	3275 (55.7)	48 (0.8)	5883
1997	790 (12.6)	587 (9.4)	1457 (23.3)	3359 (53.7)	59 (0.9)	6252
1998	987 (14.3)	603 (8.7)	1737 (25.1)	3559 (51.5)	22 (0.3)	6908
1999	1059 (15.9)	539 (8.1)	1710 (25.7)	3331 (50.0)	17 (0.3)	6656
Total	4151 (13.2)	2689 (8.6)	7624 (24.3)	16767 (53.3)	208 (0.7)	31439

Table 2 shows the neonatal outcome in relation to the mode of delivery in all the different subgroups. Characteristics of the planned CS group and the planned vaginal delivery group are shown in Table 3. Only birth weight was significantly different.

The lowest mortality was found in the planned CS (breech) group and highest mortality in the planned CS (other reasons) group. Comparing the planned vaginal delivery group with the planned CS (breech) group, mortality was twice as high (0.39% vs 0.17%), low 5-minute Apgar score seven times as high (2.8% vs 0.4%), and birth trauma three times as high (0.50% vs 0.17%) in the planned vaginal delivery group.

The birth traumas are specified in Table 4. In infants with a birth weight > 4000g, birth trauma was restricted to vaginally delivered infants (1.3%). Overall, results in these infants were similar to infants with a birth weight  $\leq$  4000g.

Table 2. Outcome by mode of delivery of infants in breech position weighing  $\leq$  4000g and > 4000g. Values are given in n (%).

	Planned CS (breech)	Planned CS (other reasons)	Emergency CS	Vaginal delivery	Planned vaginal delivery	Unknown mode of delivery	Total
≤ 4000 g					-		
n	4151	2689	7324	16767	24391	208	31439
Mortality	7 (0.17)	14 (0.52)	22 (0.29)	73 (0.43)	95 (0.39)		116 (0.37)
AS < 7	18 (0.43)	44 (1.64)	167 (2.19)	523 (3.12)	690 (2.83)	2 (0.96)	754 (2.40)
Birth trauma	7 (0.17)	3 (0.11)	17 (0.22)	105 (0.63)	122 (0.50)	2 (0.69)	134 (0.43)
> 4000 g							
n	540	276	880	673	1553	16	2385
Mortality		2 (0.7)	2 (0.2)	1 (0.1)	3 (0.2)	1 (6.3)	6 (0.3)
AS < 7		2 (0.7)	14 (1.4)	19 (2.8)	31 (2.0)	1 (6.3)	34 (1.4)
Birth trauma				9 (1.3)	9 (0.6)		9 (0.4)

Infants born by emergency CS or vaginally were also combined in the group 'planned vaginal delivery' for comparison with 'planned CS'.

Table 3. Characteristics of the planned caesarean section group and the planned vaginal delivery group. (All birth weights included).

	Planned CS	Planned vaginal
	(breech)	birth
Primiparae (%)	59	61
Multiparae (%)	41	39
Mean gestational age (weeks)	38 <sup>5</sup> / <sub>7</sub>	<b>39</b> <sup>2</sup> / <sub>7</sub>
Mean maternal age (years)	30,8	29,9
Mean birth weight (grams)	3416	3262
Infant's gender (% male)	48	45
Type of breech		
Complete (%)	26	21
Frank (%)	69	75
1 foot (%)	5	4

Table 4. Neonatal trauma in term singleton infants weighing  $\leq$  4000g and born in breech presentation, divided by mode of delivery.

	Planned CS (breech)	Planned CS (other reasons)	Emergency CS	Vaginal delivery	Unknown mode of delivery
Total number	4151	2689	7624	16767	208
Minimal 1 trauma	7	3	17	105	2
Intracerebral haemorrhage	)			3	
Cephalic haematoma					
Facial nerve palsy			1	2	
Brachial plexus lesion				29	
Fracture of clavicle			1	26	2
Fracture of humurus			1	20	
Fracture of femur			2	1	
Other trauma	7	3	12	30	

The odds ratios for neonatal mortality and morbidity in relation to the mode of delivery for infants with a birth weight  $\leq$  4000g are shown in Table 5. Parity and duration of gestation did not affect the results, but birth weight was a significant variable for mortality and Apgar score, but not for birth trauma (in those infants weighing  $\leq$  4000g). Intrapartum and neonatal mortality in the planned CS (breech) group was half that of the other group (odds ratio 0.4), but this difference was not statistically significant after correction for birth weight. When vaginal delivery and emergency CS groups were compared with total planned CS or planned CS (breech) groups, the incidence of low Apgar score was three-to-seven times lower and of birth trauma three times lower in the abdominally delivered groups. These differences were significant.

With respect to gender differences, overall mortality irrespective of the mode of delivery was significantly higher in boys than in girls (0.45% *vs* 0.28%; OR 1.63; 95%-CI 1.13-2.34), so was a 5-minuten AS kleiner dan 7 (2.77% *vs* 1.96%; OR 1.42; 95%-CI 1.23-1.64). This worse outcome for boys was also observed in the planned vaginal delivery group with mortality rates for boys and girls of 0.36% *vs* 0.22%, respectively (OR 1.67; 95%-CI 1.11-2.50) and low AS for boys and girls of 2.51% *vs* 1.81%, respectively (OR 1.44; 95%-CI 1.24-1.68). In the planned CS groups the same trend was observed, but due to small numbers no significance was reached. (NB. This paragraph was not included in the original article).

Table 5. Crude and corrected\* odds ratios and 95% confidence intervals (CI) per neonatal outcome for term singleton infants in breech presentation delivered by planned caesarean section, compared with infants born after planned vaginal delivery (data restricted to birth weight ≤ 4000g).

	Neonatal outcome	Odds ratios	95%-CI	After correction for birth weight	
				Odds ratios	95%-CI
Planned CS (total)  vs  planned vaginal	Mortality	0.79	0.50-1.28	0.83	0.52-1.34
	Apgar score < 7	0.32	0.24-0.41	0.33	0.25-0.43
delivery	Birth trauma	0.29	0.15-0.55		
Planned CS (breech)	Mortality	0.43	0.20-0.94	0.59	0.26-1.21
<i>vs</i> planned vaginal	Apgar score < 7	0.15	0.09-0.24	0.17	0.11-0.27
delivery	Birth trauma	0.33	0.16-0.71		

<sup>\*</sup> Corrected for birth weight.

Analysis of the subgroup of infants born before 41 weeks of gestation and with whom no oxytocic drugs were used to induce or to augment labour showed that mortality (0.2% and 0.3%, respectively), low Apgar score (0.4% and 2.5%, respectively) and birth trauma (0.2% and 0.5%, respectively) were significantly lower in the planned CS (breech) group as compared to the planned vaginal delivery group (i.e. vaginal delivery and emergency CS) (data not shown).

Subdividing all 119 Dutch hospitals into 3 groups according to their incidence of overall planned CS for breech presentation (0 - 17%; 17% - 26% and > 26%) showed identical results in all 3 groups, with a lower mortality rate and incidence of low Apgar score and birth trauma in the total planned CS group as well as in the planned CS (breech) group compared to the planned vaginal delivery group (data not shown).

Finally, complications with the after-coming head increased with the duration of the second stage: in 13% of vaginally delivered neonates with a second stage  $\leq$  30 minutes, in 16% when it lasted between 30-60 minutes, and in 20% when it lasted between 60-90 minutes. Assistance with forceps on the after-coming head was clearly related to a significantly higher mortality (1.0% vs 0.3%), low Apgar score (9.2% vs 2.1%) and birth trauma (1.9% vs 0.4%) compared with spontaneous birth of the head.

#### DISCUSSION

For several decades, researchers have tried to assess the best possible route of delivery for the term breech presentation, resulting in a multitude of published reports and trials. The first article to analyse outcome by intended and not by actual method of delivery, based on a literature search and on original data, was by Bingham and Lilford<sup>6</sup> and was later updated by Cheng and Hannah.<sup>7</sup> The data of our large observational study is in agreement with these articles and shows poorer outcome in the planned vaginal birth group, just as was found in the randomised study by Hannah *et al.*<sup>1</sup> Britton *et al.*<sup>8</sup> have extensively explored the process of randomisation in contrast with non randomised studies and found that the latter studies often produce very similar results.

In The Netherlands, for many years, perinatal data has been prospectively coded by obstetricians and such coding occurred well before a specific interest emerged about the relationship between neonatal mortality and morbidity and mode of delivery in breech presentations. Bias in coding seems, therefore, highly unlikely.

Our study is hampered because we do not know the indications for planned CS or planned vaginal birth for the individual patient. On the other hand, all cases of breech presentation were included in this population based study. This is an advantage over the Term Breech Trial, to which many centres only contributed a few cases, which suggests that many cases of breech position in those centres were not recruited ('recruitment bias').

The distinction between planned CS (because of breech) and planned CS (for other reasons) appears to be of great importance. Planned caesarean section specifically for breech has a lower relative risk of an adverse outcome compared with planned vaginal delivery, than when including all cases (see Table 5). This is obvious by the differences in mortality and low Apgar scores between both comparisons and suggests that breech position was indeed the only reason for performing a CS in the planned CS (because of breech) group. The higher mortality and higher rate of low Apgar score in the comparison using the total planned CS group (odds ratios twice as high) may be explained by preexisting fetal problems. Birth trauma occurred at a similar incidence in the total planned CS group as in the planned CS (breech) group and this seems logical, as it is unlikely to be related to the indication for CS. It should be noted that the authors of this study did not classify the indication for planned CS, but that the attending obstetrician did this at the time CS took place. The lower relative risk in the group 'CS because of breech position only' increases the plausibility that there are indeed genuine differences in mortality and morbidity, according to the intended method of delivery, regardless of any other confounding factors.

This data shows a two-fold increase in mortality, a seven-fold increase in low Apgar score and a three-fold increase in birth trauma, following vaginal delivery or emergency CS in cases of breech position compared with planned CS for breech presentation. After correcting for birth weight, the difference in mortality was no longer significant. This seems of no great clinical significance, since antenatal prediction of birth weight is very inaccurate and retrospective adjustment for knowledge which will only be acquired after the decision has been taken, is of limited value.

A sub-analysis on the group with gestational age < 41 weeks in which no oxytocic drugs were used was carried out to examine whether vaginal delivery might be safe under strict conditions. Neonatal outcome, both for mortality and for morbidity, remained significantly worse for the planned vaginal birth group; therefore, case selection using these criteria appears to make no difference.

In vaginal breech delivery, the highest neonatal morbidity and mortality occurred with complications with the after-coming head and in long second stages, which is no great surprise.

Planned CS has a greater effect on neonatal outcome in countries with a low perinatal death rate than in countries with high death rates. This would suggest that the effects of a planned CS would be greater in our population than those found by Hannah et al. However, both studies show favourable effects attributable to planned CS, but this was less evident among our population. This may be explained by the overall high percentage of term breeches among our hospital population (8.2%), which is twice as high as in other countries (< 4%).1 This is due to the selection system existent in The Netherlands, whereby low-risk pregnancies are seen by independent midwives and high-risk pregnancies by gynaecologists. This results in a concentration of high-risk pregnancies in hospitals and in a high level of expertise with respect to vaginal breech deliveries. Moreover, until 1999 all gynaecologists had a considerable experience with vaginal term breech deliveries, as the overall vaginal delivery rate in term breeches was about 50% at that time; this may be different from the centres participating in the Hannah study. In the latter study there were 126 participating centres, with 65 who included less than 10 patients of whom 12 including only 1 patient. Nevertheless, our results are consistent with the findings of Hannah et al. and indicate a lower neonatal mortality and morbidity, when term breeches are delivered by planned CS.

A low 5-minute Apgar score is associated with later neonatal mortality and morbidity, <sup>4,5</sup> but follow-up of the infants involved in the Term Breech Trial is still necessary to substantiate possible differences in later outcome.

The results of such studies, however, also have to be weighed against possible increased maternal risks due to CS. Caesarean section has been associated with a two- to elevenfold increased risk of maternal death. When a correction was made for confounding factors by classifying a group of previously healthy women, Moldin *et al.* found a twelvefold increased risk for emergency CS and a four-fold increased risk for planned CS compared to vaginal delivery. By subdividing death in direct and incidental or indirect, Lilford *et al.* described the relative risk of direct maternal death associated with caesarean section compared with vaginal delivery to be 4.7, with a relative risk of 1.4 of intrapartum *vs* elective surgery.

Maternal morbidity associated with caesarean section might be up to five-to-ten times that of vaginal birth, 10,14 most commonly manifest by infection, followed by blood transfusion. Infection is less likely following planned surgery than after an emergency intrapartum CS, but is still significantly higher than after vaginal birth. Long term complications include uterine rupture and placental invasion of the uterine scar during subsequent pregnancies, 15-19 frequently leading to neonatal mortality or major maternal morbidity, such as severe haemorrhage and hysterectomy.

Finally, neonatal morbidity has been described to be higher in abdominal delivery, due to pulmonary problems such as respiratory distress syndrome, caused by iatrogenic preterm birth.<sup>10</sup> If timing of the CS is properly done, this should not occur.

#### CONCLUSION

The data from this nation-wide Dutch Perinatal Database shows an increase in early neonatal morbidity and mortality, following a trial of labour in cases of term breech presentation, when compared with a planned SC and confirms the results of Hannah *et al.* This data requires carefully weighed consideration against increased maternal (long term) risks due to a rise in caesarean sections.

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# 3

The effect of the Term Breech Trial on medical intervention behaviour and neonatal outcome in The Netherlands:

an analysis of 35,453 term breech infants

Christine C.Th. Rietberg
Patty M. Elferink-Stinkens
Gerard H.A. Visser

#### **ABSTRACT**

**Objective:** To examine the effects of the Term Breech Trial on the medical behaviour of Dutch obstetricians and on neonatal outcome.

Design: retrospective observational study.

**Setting:** The Netherlands.

**Population:** Infants born at term in breech presentation in The Netherlands between 1998 and 2002, with birth weights  $\leq$  4000g (n=33,024) and > 4000g (n=2,429), respectively. Multiple pregnancies, antenatal death and major congenital malformations were excluded.

**Methods:** Data derived from the Dutch Perinatal Database was used to compare modes of delivery and neonatal outcome of infants born in breech position in the 33 months preceding publication of the Term Breech Trial and in the 25 months thereafter.

**Main outcome measures:** Incidence of planned and emergency caesarean section, vaginal breech delivery, perinatal death, 5-minute Apgar score and birth trauma.

**Results:** Within two months after publication of the Term Breech Trial, the overall caesarean rate increased from 50% to 80% and has remained stable thereafter. In the group of infants  $\leq$  4000g this was associated with a significant decrease of perinatal mortality from 0.35% to 0.18%, a decrease of the incidence of 5-minute Apgar score < 7 from 2.4% to 1.1% and a decrease of birth trauma from 0.29% to 0.08%. In the (small) group of infants > 4000g a similar trend was observed.

**Conclusions:** The Term Breech Trial has resulted in an exceptionally rapid change in medical behaviour by Dutch obstetricians. This change has resulted in improved neonatal outcome.

#### INTRODUCTION

In October 2000, the results of the Term Breech Trial (TBT)<sup>1</sup> were published in the Lancet. This prospective randomised trial consisted of approximately 2000 pregnant women at term with a fetus in breech position. It was concluded that a policy of a planned caesarean section (CS) led to a significantly better direct neonatal outcome compared with a planned vaginal delivery and that this was not associated with a greater maternal morbidity until 6 weeks after delivery. In June 2003, we published a retrospective population-based study on the outcome of all 33,824 term breech deliveries in The Netherlands from 1995 - 1999.<sup>2</sup> Vaginal delivery and emergency CS resulted in a seven-fold increase in low 5-minute Apgar score, a three-fold increase in birth trauma and a two-fold increase in perinatal death when compared with the results of planned CS, thus confirming the results of the Term Breech Trial.

Publication of the TBT has resulted in an increase of planned CS in centres that took part in this trial<sup>3</sup> and in The Netherlands the overall CS rate of term breeches increased from 50% in 2000 to 80% in 2001.<sup>4</sup>

The purpose of this study is to investigate the time scale in which this change in obstetric management occurred and whether or not it occurred in all hospitals. We were also interested to find out whether this change persisted during the following years. Most of all, we wanted to study whether this change in management was related to improved direct neonatal outcome.

For this study we derived data from The Netherlands Perinatal Registry on more than 33,000 term infants, born in breech position between 1998 – 2002.

# **METHODS**

The Netherlands Perinatal Registry includes 95% of all approximately 200,000 deliveries per year in The Netherlands. This includes both deliveries under the supervision of midwives and general practitioners (low risk: primary care) and deliveries under the responsibility of gynaecologists (high risk: secondary care). Because only a few secondary care departments with a small number of deliveries do not participate, the registry covers almost 100% of secondary care deliveries. All infants in breech position are born under secondary care. The registration of secondary care deliveries (Landelijke Verloskunde Registratie-2; LVR-2) was set up in 1982 for all secondary care obstetric departments. This set up was preceeded by a 10-year trial period, during which a limited number of departments participated in a pilot study. Eleven clinics used a uniform registry

system coding about 80 obstetric items. This preliminary registry was extensively investigated and validated. Computerised error checks strongly improved the validity of the system<sup>6</sup> before it was introduced to all Dutch hospitals. An electronically extracted discharge letter to the general practitioner and other specialists positively influenced the registry. Reliability of the present LVR registry was further tested in recent years and is now even used extensively for peer review among Dutch departments.<sup>7-10</sup>

In the LVR-2, the indications for planned CS (i.e. with no intended trial of labour) are registered for every patient in this category. The indications are subdivided in the following categories: 'elective', 'condition of the mother', 'condition of the fetus', 'condition of the mother and fetus', or 'unknown'. In this way, specific fetal problems (such as fetal growth retardation or signs of antenatal asphyxia) are coded separately. The category 'elective' is hereby reserved for planned CS due to breech position only, without additional pathology. In 0.4% of cases, the mode of delivery was not coded. Comparison of the planned CS (due to breech position only) subgroup, with the combined vaginal delivery and emergency CS (during labour) subgroups (i.e. planned vaginal delivery group), may reveal differences in outcome according to the chosen policy, as was done in chapter 2.2 In order to enable comparison with the data of the TBT, we included infants in breech presentation who were delivered at term (between 37-41 weeks of gestation) with birth weights ≤ 4000g as we did in chapter 2. Exclusion criteria were multiple pregnancy, antenatal fetal death and major congenital malformations (central nervous system abnormalities, such as spina bifida, meningomyelocele, exencephaly, anencephaly, hydrocephaly and microcephaly and infants with multiple congenital malformations, including intestinal atresias and congenital heart disease).

In a separate analysis, we studied the group of children with a birth weight > 4000g.

# Outcome measures were

- 1. Perinatal mortality: this was defined as intrapartum death or death within a week following birth.
- 2. Five-minute Apgar score: this score was subdivided as either < 7 or ≥ 7, according to reports from Sweden and Norway on prediction of long term neonatal morbidity.<sup>11,12</sup>
- 3. Neonatal trauma: this was classified as intracerebral haemorrhage, cephalic haematoma, facial nerve palsy, brachial plexus lesion, fracture of clavicle, humerus or femur and other trauma.

A comparison was made for perinatal mortality, low Apgar score and trauma between the period before the Term Breech Trial and the period after, using exact numbers, percentages and odds ratios. The period before the TBT was defined as the years 1998, 1999 and part of 2000 (until September 30; the Trial was published in October 2000). The period after the TBT started at 1st December 2000 and included the years 2001 and 2002. For trend analysis of vaginal delivery and CS rate, data from 1995 - 2002 was used.

#### **RESULTS**

Figure 1 shows the trends in vaginal delivery and CS in women with an infant in breech presentation between 1995 and 2002. Figure 2 shows a more detailed month-to-month trend between January 2000 and December 2002. In the first two months following publication of the TBT, there was an increase in total CS rate from 50% to over 80% and this rate has remained stable thereafter. This rise was mainly due to an increase in planned CS. Emergency CS decreased slightly.

The increase in CS rate after publication of the TBT was observed in all but three hospitals in The Netherlands and the proportional increase in CS rate was more or less similar in hospitals with an initial low or high CS rate.

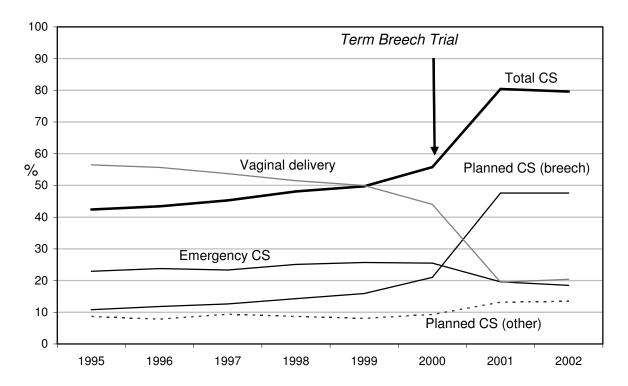


Figure 1. Trends in vaginal delivery and caesarean section in women with a term singleton infant in breech presentation between 1995 – 2002.

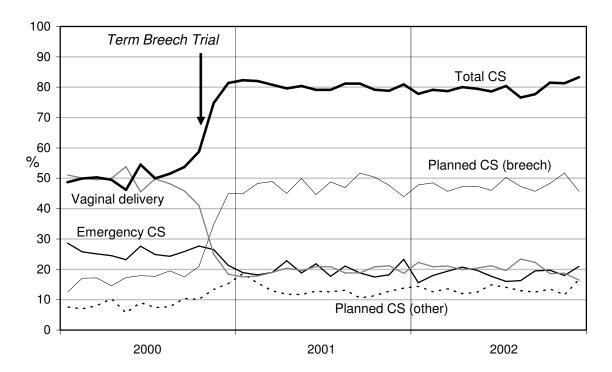


Figure 2. Percentages of different modes of delivery in women with a term singleton infant in breech presentation preceding and following the publication of the Term Breech Trial in October 2000.

Table 1. Neonatal outcome following term breech delivery in The Netherlands in the 33 months before publication of the Term Breech Trial (TBT) and in the 25 months thereafter. Values are given in n (%).

	Before TBT 1998 – Sept 2000	After TBT Dec 2000 – 2002	Odds ratios (95%-CI)	р
Birth weight ≤ 4000 g				
n	18766	14258		
Perinatal mortality	65 (0.35)	26 (0.18)	0.53 (0.33-0.83)	0.007
5-minute Apgar score < 7	449 (2.4)	149 (1.1)	0.43 (0.36-0.52)	< 0.0001
Birth trauma	55 (0.29)	11 (0.08)	0.26 (0.14-0.50)	< 0.0001
Birth weight > 4000 g				
n	1449	980		
Perinatal mortality	5 (0.35)	1 (0.10)	0.3 (0.03-2.53)	
5-minute Apgar score < 7	24 (1.66)	11 (1.12)	0.68 (0.33-1.38)	
Birth trauma	4 (0.28)	2 (0.20)	0.74 (0.14-4.04)	

Table 1 shows neonatal outcome following term breech delivery in The Netherlands in infants weighing  $\leq$  4000g in the 33 months before publication of the TBT and in the 25 months thereafter. There was a two-fold decrease in perinatal death and in low 5-minute Apgar score and an almost fourfold decrease in neonatal trauma.

Table 2. Neonatal outcome after different modes of delivery in the term breech presentation in the 33 months before the Term Breech Trial (n = 18,766) compared with the 25 months thereafter (n = 14,258). Birth weight  $\leq 4000g$ . Values are given in n (%).

	Planned CS (breech)  before after		Planned (	CS (other)	Emerge	ncy CS	Vaginal delivery		
TBT			before	after	before	after	before	after	
	2992	6773	1564	1909	4776	2731	9454	2835	
Mortality	2 (0.07)	4 (0.06)	8 (0.51)	5 (0.26)	18 (0.38)	3 (0.11)	37 (0.39)	14 (0.49)	
AS < 7	11 (0.38)	22 (0.33)	23 (1.47)	13 (0.68)	109 (2.28)	41 (1.50)	306 (3.24)	73 (2.57)	
Trauma	4 (0.14)	3 (0.04)		1 (0.05)	6 (0.13)	1 (0.04)	45 (0.48)	6 (0.21)	

In 60 cases the mode of delivery was unknown.

This decrease can mainly be attributed to the increase in planned CS because of breech position, as this mode of delivery was associated with the lowest mortality and morbidity, both before and after the TBT (Table 2). After the publication of the TBT, the neonatal outcome after emergency CS also seemed to have improved but this was only significant for low Apgar score (p = 0.025). A lower incidence of birth trauma in the vaginal delivery group after the TBT did not reach statistical significance (Table 2).

Infants > 4000g were already predominantly delivered by CS before the TBT (74%). After publication of the TBT this percentage increased to 89%. Also in this subgroup there was a trend towards a better outcome after the TBT. However, this did not reach statistical significance, most likely due to the small numbers (Table 1).

#### DISCUSSION

This study has shown that the CS rate for babies at term with breech presentation in The Netherlands was increased from 50% to 80% within two months after publication of the TBT. This increase in CS rate occurred in almost all Dutch hospitals. This change in

policy was accompanied by a significant decrease in perinatal mortality from 0.35% to 0.18%.

In our opinion, such a rapid and radical change in medical treatment behaviour is quite exceptional. Studies on medical treatment behavioural pattern and physicians' attitudes show that it normally takes several years to change attitudes and behavioural patterns after new viewpoints have been published. The reasons for the abrupt change as found in this study are unclear\*. On the one hand, this may be due to the recommendation of the Dutch Society of Obstetrics and Gynaecology advising obstetricians to include the results of the TBT in counselling their patients. On the other hand, it may well be that in a 'Calvinistic' country like The Netherlands obstetricians needed a trial like the TBT to change practice.

The TBT was stopped prematurely in April 1999 and the reasons for this were widely known. It is noteworthy that the preliminary conclusions did not change clinical behaviour among Dutch obstetricians while the formal publication did.

The improved outcome is likely to be due to the increase in planned CS, but outcome was also slightly better following emergency CS and vaginal delivery. This may indicate that the decision to perform an emergency CS was made earlier after the TBT and that the remaining 20% vaginal breech deliveries constitute a better selection of the population for such a method of delivery or very short labours with insufficient time to arrange for a timely CS.

Immediate follow-up studies after a randomised controlled study seldom show improvements in clinical outcome. This may either be due to a lack of change in medical behaviour or to differences between trial circumstances and the actual clinical situation. Our study clearly shows that the TBT resulted in changes in medical behaviour and an improvement in clinical outcome. It is likely that the latter is related to the publication of the TBT because there had not been significant changes in outcome during the five years preceding the trial.

An increase in CS from 50% to 80% and a decrease in perinatal mortality from 0.35% to 0.18% means that approximately 175 extra caesarean sections will have to be performed to prevent one perinatal death. This figure has to be weighed against an increased risk of

<sup>\*</sup> See the results of our later study into these reasons, presented in Chapter 5.

maternal morbidity and mortality due to the caesarean section and an increased maternal and fetal risk in subsequent pregnancies, <sup>17</sup> especially uterine rupture <sup>18-22</sup> and placental invasion of the uterine scar during subsequent pregnancies. <sup>23-28</sup>

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# 4

Increased neonatal morbidity and mortality after vaginal trial of labor: a study in 11,080 term breeches

Christine C.Th. Rietberg
Patty M. Elferink-Stinkens
Floris Groenendaal
Gerard H.A. Visser

# Submitted

#### **ABSTRACT**

**Objective:** To study perinatal mortality and severe neonatal morbidity in singleton term breech fetuses delivered by elective caesarean section (CS) or after a vaginal trial of labour (VTOL) in The Netherlands.

**Methods:** Singleton infants (n=11,580) without congenital malformations born between 37 - 41 weeks during the period 2001 - 2003 were studied, using a linked perinatal registry, covering 70% of all Dutch births. Planned vaginal delivery (vaginal delivery plus emergency CS) was compared with planned elective CS (for breech presentation only). Perinatal mortality and neonatal morbidity were studied in relation to mode of delivery, parity, gestational age, gender and birth weight, using logistic regression.

**Results:** Perinatal mortality was 0.38% after VTOL and 0% after elective CS. After vaginal delivery severe morbidity predominated (1.35% compared with 0.48% after emergency CS and 0.16% after elective CS). Combined mortality / severe morbidity occurred in 1.29% after VTOL and in 0.16% after elective CS. Wet lung occurred significantly more often after elective CS (1.45% compared with 0.87% after VTOL; OR 1.67; 95%-CI 1.13-2.48). Hyperbilirubinaemia, need for resuscitation and 5-minute Apgar scores < 4 were significantly higher after VTOL. In the vaginal group highest mortality / morbidity occurred for infants < 2500g. Mode of delivery and low birth weight were significant factors influencing neonatal morbidity. There was a trend for adverse outcome in males (RR 1.6; 95%-CI 0.98-2.65), with no difference for parity or gestational age.

**Conclusion:** perinatal mortality and morbidity are higher with VTOL than with planned elective CS, with poorest outcome in infants < 2500g.

#### INTRODUCTION

The multicenter / multinational Term Breech Trial (TBT) has shown that direct perinatal outcome after planned caesarean section (CS) was better than after trial of labour. However, due to large inter-institutional variations in standards of care, low recruitment in participating centres and under-powering in countries with low perinatal mortality, validity of the conclusions has recently been questioned. With respect to the different drawbacks of RCT's in obstetric practice, observational population studies with robust numbers might be more likely capable to answer questions regarding the (un)safety of a trial of labour in case of breech position.

In chapter 2 we have shown that perinatal mortality was more than twice as low in elective CS, compared with a vaginal trial of labour (based on 33,000 term breech deliveries in The Netherlands in the period 1995-1999).<sup>3</sup> Moreover, in chapter 3 we showed that an increase in CS rate from 50% to 80%, which occurred in The Netherlands after publication of the TBT, resulted in a 50% reduction in perinatal mortality.<sup>4</sup>

Our current study investigates differences in perinatal outcome and especially in severe neonatal morbidity between elective CS and vaginal trial of labour. By combining obstetric and neonatal databases, we were able to analyse this on the basis of 11,580 term breeches, delivered in the 3-year period 2001 – 2003.

#### MATERIALS AND METHODS

For the years 2001, 2002 and 2003 data from the National Obstetric Database (LVR-2) could be linked to data from the National Neonatal Database (LNR). This data was obtained from The Netherlands Perinatal Registry. All Dutch hospitals participate in the registration of obstetric secondary care. About 70% of those, including all ten level III neonatal intensive care units, also participate in the registration of neonatal data. Yearly a total of approximately 200,000 infants are born in The Netherlands, of which 3%-4% in breech position.

In the period covered by our study, 14,048 infants born in breech position were registered in the linked perinatal database. This is about two-thirds of all infants born in breech position in The Netherlands in that period. Of these, 11,580 were singleton, without congenital malformations and born between 37-41 weeks. These are the subjects of our present analysis. Sub-analyses were performed on male and female gender.

Four different modes of delivery were analysed: planned elective CS, planned CS for other reasons, emergency CS and vaginal delivery. The coding 'planned elective CS' was used only for a CS performed because of breech presentation. Therefore, this group

represents an otherwise healthy group of infants without additional pathology. The vaginal delivery group and emergency CS group were analysed separately and thereafter combined as a 'vaginal trial of labour' group (VTOL) and compared to the 'elective CS' group.

Infant mortality was subdivided into mortality during labour and neonatal mortality until 28 days after delivery (or longer if the child stayed admitted longer). Antenatal mortality was excluded. In the neonatal mortality group no additional morbidity was recorded.

Neonatal morbidity for the surviving infants was defined as: seizures, hypoxic-ischemic encephalopathy (HIE) (grade 1, 2 or 3, according to Sarnat classification<sup>5</sup>), traumatic haemorrhage, such as cephalic, subdural, subarachnoidal haematoma and tentorial rupture, fractures and paralyses, low 5-minute Apgar scores of < 4 and < 7, hyperbilirubinaemia (defined as the need for photo therapy), pulmonary morbidity (wet lung, Idiopathic Respiratory Distress Syndrome, pneumothorax). Severe neonatal morbidity other than pulmonary was considered present when either seizures, encephalopathy grade 1, 2 or 3, traumatic haemorrhage and / or fractures and paralyses had been diagnosed. The need for resuscitation, defined as resuscitation with bag and mask ventilation or endotracheal intubation and ventilation, was studied for both the VTOL and the elective CS groups.

To investigate the impact of birth weight on morbidity we stratified for weight, using the categories < 2500, 2500-2999, 3000-3499, 3500-3999, 4000-4499 and ≥4500g.

A logistic regression model was used in which mode of delivery, parity (multi-parity to primi-parity [first born infant]), gestational age, gender and birth weight were analysed.

# **RESULTS**

In Table 1 perinatal outcome is shown for the four different modes of delivery and for VTOL. Mean gestational age at delivery was slightly lower in the elective-CS group (38.8 weeks, SD 0.8) and in the CS-other group (38.7 weeks, SD 0.9), than in the vaginal delivery (39.5 weeks, SD 1.2) and emergency-CS groups (39.3 weeks, SD 1.3). Mean birth weight was about the same for all groups, with the lowest birth weight in the vaginal delivery group (mean 3198g, SD 430g) and the highest weight in the emergency CS group (mean 3316g, SD 498g). Intrapartum and neonatal mortality was 0.38% in the VTOL group as compared to 0% in the elective CS group. Severe morbidity was present in 1.35% of infants born vaginally, in 0.48% delivered by emergency CS (total VTOL 0.92%), in contrast to 0.16% in the elective CS group. Mortality and severe morbidity together occurred in 1.29% after VTOL and in 0.16% after elective CS, i.e. a difference of

more than one percent. Outcome of infants after a CS for other reasons showed a combined mortality / morbidity of 0.56%.

Detailed analysis of mortality showed fetal asphyxia in all 7 cases of intrapartum death, in 1 case this was due to a uterine rupture. In all cases neonatal death occurred within 7 days, and was due to asphyxia (n=8), mild asphyxia with sepsis (n=1) or unknown reasons (n=1). The latter child was delivered by CS for other reasons, had a birth

Table 1. Perinatal mortality and morbidity for singleton term infants (37 - 41 weeks) in breech presentation in relation to mode of delivery. Values are given in absolute numbers and percentages.

				.,	Emerg.	\ <del>(T</del> O)	Elective		<b>-</b>
			Total is	Vaginal	CS	VTOL	CS	CS other	Total
		induces automa	Total n	2154	2103	4257	5524	1799	11580
		intrapartum	n	5	2	7	0	0	7
М	neonatal Mortality		n	6	3	9	0	1	10
			total	11	5	16	0	1	17
			%	0.51	0.24	0.38	-	0.06	0.15
	Se	eizures	n	7	9	16	2	6	24
			%	0.33	0.43	0.38	0.04	0.33	0.21
		fracture	n	9	0	9	5	0	14
Severe morbidity in surviving infants		ii dotai o	%	0.42	-	0.21	0.09	-	0.12
ginf	Trauma	paralysis hemorrhage	n	15	0	15	2	2	19
ivi			%	0.70	-	0.35	0.04	0.11	0.16
sur			n	1	0	1	0	0	1
.⊑			%	0.05	-	0.02	-	-	0.01
oidity		grade I	n	4	2	6	0	2	8
nork		grade II	n	3	3	6	0	2	8
ere r	HIE	grade III	n	1	0	1	0	0	1
Seve			total	8	5	13	0	4	17
			%	0.37	0.24	0.31	-	0.22	0.15
	n infa	nts severe	total	29	10	39	9	9	57
	mo	orbidity	%	1.35	0.48	0.92	0.16	0.50	0.49
Perin	atal death	or at least 1	total	40	15	55	9	10	74
	severe mo	rbidity	%	1.86	0.71	1.29	0.16	0.56	0.64

CS = caesarean section. VTOL = vaginal trial of labour (combination of the vaginal delivery and emergency CS subgroup). H I E = hypoxic-ischemic encephalopathy.

weight of 2980g at 37 <sup>5</sup>/<sub>7</sub> weeks, a 5-minute Apgar score of 10 and died two days after delivery because of unknown reasons. Both sepsis or a metabolic disorder may have caused the sudden deterioration, but permission for a post mortem examination was not obtained. Table 2 shows the most likely causes for perinatal death and neurological morbidity (i.e. seizures; HIE; cerebral haemorrhage). The excess of mortality and morbidity in the VTOL group was due to fetal asphyxia, in some cases combined with a difficult and traumatic vaginal delivery.

Fractures were more common after vaginal delivery. However, fractures in the planned CS group were more severe [(clavicle (n=1), femur (n=3), humerus (n=1)], as compared to [clavicle (n=9), humerus (n=1)] the vaginal group.

Table 2. Most likely causes for perinatal death (n=17) and neurological morbidity (seizures; HIE; cerebral haemorrhage; n=31).

	n	Asphyxia	Infection	Diabetes*	Drug abuse	Unknown
Vaginal delivery	23	21	2			
Emergency CS	15	12		1		2
Elective CS	2				1	1
CS other	8	1		3		4

CS = caesarean section. \* neonatal seizures because of hypoglycaemia

Table 3. Pulmonary morbidity and low Apgar scores < 4 and < 7 at 5 minutes for singleton term infants in breech presentation in relation to mode of delivery. Values are given in absolute numbers and percentages.

	-		Р	5-minute Apgar score							
Mode of delivery	n		IRDS	pneu	ımothorax	we	t lung	< 4	%	< 7	%
Vaginal delivery	2149	0	0.00%	3	0.14%	15	0.70%	10	0.47%	54	2.51%
Emergency CS	2101	3	0.14%	2	0.10%	22	1.05%	3	0.14%	26	1.24%
VTOL	4250	3	0.07%	5	0.12%	37	0.87%	13	0.31%	80	1.88%
Elective CS	5524	3	0.05%	6	0.11%	80	1.45%	1	0.02%	8	0.14%
CS other	1799	3	0.17%	0	0.00%	32	1.78%	2	0.11%	8	0.44%
Total	11573	9	0.08%	11	0.10%	149	1.29%	16	0.14%	96	0.83%

CS = caesarean section. VTOL = vaginal trial of labour (combination of the vaginal delivery and emergency CS subgroup). IRDS = idiopathic respiratory distress syndrome.

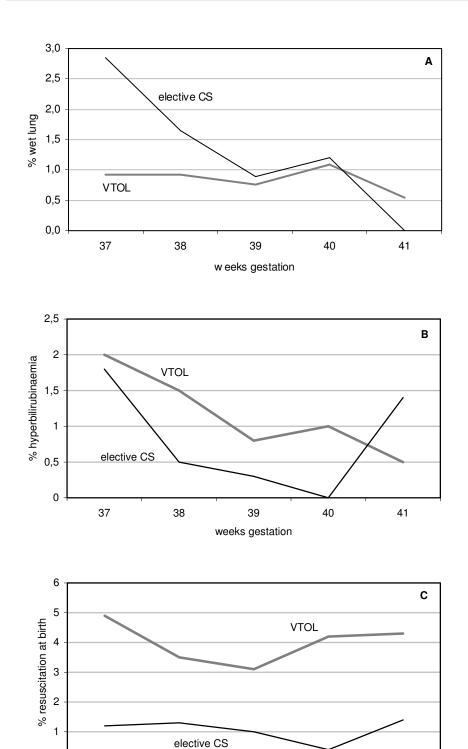


Figure 1. Wet lung (A), hyperbilirubinaemia (B) and necessity for resuscitation at birth (C) after vaginal trial of labour (VTOL) and elective caesarean section (CS) for singleton term infants in breech position.

weeks gestation

Pulmonary morbidity and Apgar scores are shown in Table 3. For IRDS and pneumothorax no difference was found between VTOL and elective CS, but wet lung occurred significantly more often after elective CS (1.45% as compared to 0.87% in VTOL; OR 1.67; 95%-CI 1.13-2.48).

The percentage of 5-minute Apgar scores < 4 in VTOL group was 0.31% as compared to 0.02% in the elective CS group (OR 17.0; CI 2.22-129.59).

Also the difference in percentage of 5-minute Apgar scores < 7 between the VTOL group as compared to the elective CS group was highly significant (1.58% and 0.13%, respec-

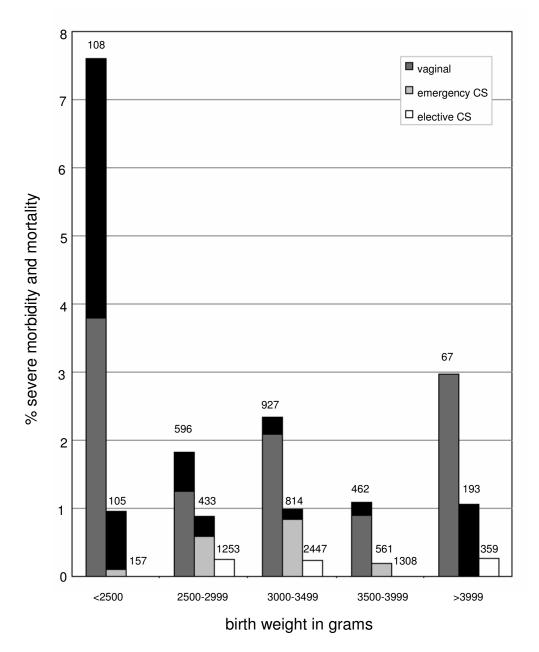


Figure 2. Incidence of severe morbidity and mortality (in black) after vaginal delivery, emergency CS and planned elective CS in singleton term breech infants in relation to birth weight. Digits at the top indicate number of infants per group.

tively; OR 12.62; CI 5.79-27.53). For these analyses intrapartum deaths were excluded. In Figure 1 total pulmonary morbidity is shown per week of gestation for VTOL and for elective CS. The excess of pulmonary morbidity in the latter group only occurred at 37 and 38 weeks of gestation. Hyperbilirubinaemia and need for resuscitation at birth were higher after VTOL at all gestational ages (Figure 1).

Stratification for birth weight showed that morbidity and mortality was highest for the vaginal delivery group for all weight categories (Figure 2). In the vaginal delivery group highest combined mortality and morbidity occurred in infants < 2500g (8 of 108 infants), without specific trends in the other weight categories. In the other modes of delivery there was no relationship between birth weight and prevalence of severe morbidity / mortality. Finally a logistic regression model was used to analyse the effect of mode of delivery, parity, gestational age, gender and birth weight (Table 4). Mode of delivery and low birth weight were significant factors influencing neonatal morbidity. Gender almost reached significance (morbidity / mortality in males as compared to females, RR 1.6; 95%-Cl 0.98-2.65). No difference was seen for parity or gestational age.

Table 4. Logistic regression model with mode of delivery, gender, parity, gestational age and birth weight in relation to mortality or severe neonatal morbidity. The reference group for birth weight is 2500 – 4000g.

	OR	95%-CI
Planned elective CS versus VTOL	0.13	0.06 - 0.26
gender: male versus female	1.61	0.98 - 2.65
parity: multi versus primiparae	1.23	0.75 - 2.02
gestational age (per week)	0.97	0.78 - 1.20
birth weight < 2500g versus 2500-4000g	3.09	1.45 - 6.59
birth weight ≥ 4000g versus 2500-4000g	1.43	0.57 - 3.61

OR = odds ratios. CI = confidence interval. CS = caesarean section. VTOL = vaginal trial of labour.

# **DISCUSSION**

To study long-term consequences of infant morbidity after breech birth large cohorts of infants should be followed for a long period of time. Although 2-year follow-up data was reported by the Term Breech Trial collaborative group, its sample size was too small to draw conclusions on planned caesarean birth and long term paediatric morbidity.<sup>6</sup>

In our study we were able to analyse a cohort of more than 11.000 term singleton infants in breech position. The drawback of observational studies like this one is that no conclusions can be drawn about the eligibility of the individual patient. However, the positive aspect of our study is the lack of selection bias. Two-thirds of all breech infants in The Netherlands (defined by the hospitals participating in the Dutch Neonatal Registry) were allocated for our analysis. The distribution of these hospitals was random across the country.

Our previous study in chapter 3 showed an improvement in neonatal outcome of term breech infants in The Netherlands after the remarkable rise in CS rate from 50% to 80% in the two months following publication of the TBT. Mortality dropped from 0.35% to 0.18%, low 5-minute Apgar score and trauma dropped from 2.4% to 1.1% and from 0.29% to 0.08% respectively. Although the present study was carried out with data dealing with this new policy (after the year 2000) and therefore with a lower adverse perinatal outcome, again the same conclusions can be drawn as in the Term Breech Trial and in our previous study. Planned vaginal delivery carried a risk of perinatal mortality of 0.38%, while in the planned elective CS group no mortality occurred. Severe neonatal morbidity occurred in 0.92% in the planned vaginal delivery group versus 0.16% in the CS group. Mortality or severe neonatal morbidity, when combined, occurred in 1.29% in the planned vaginal delivery group as compared to 0.16% in the planned elective CS group. This means a surplus of serious problems of more than 1% after planned vaginal delivery.

Possibly the 'vaginal delivery' group is negatively influenced by the results of some women, in whom beforehand a planned caesarean section had been scheduled, which could not be done because of a very rapid progress of labour. In these cases the baby could be deprived, resulting in serious morbidity or even mortality and this would be registered under 'vaginal delivery', even though a vaginal delivery had not been planned. However, the mean duration of the second stage of labour in this group showed the opposite: both in primiparae and in multiparae a significantly longer second stage had been present in infants who died or suffered severe morbidity, than in infants born vaginally without severe complications. Detailed analysis of all 57 infants with serious morbidity or mortality showed only one case in which a rapid progress of labour may have played a role.

The vaginal group may also have been negatively affected by cases in with other pathology had been present, such as small-for-dates, maternal diabetes or fetal

macrosomia. In a randomised trial these cases would probably have been excluded from randomisation because of this additional pathology. Detailed analysis in our study revealed that in several cases of severe neonatal morbidity a questionable choice had been made for a vaginal delivery, even though additional perinatal risk was present. If in these cases a CS would have been performed, morbidity would have been registered in the CS-other group instead of in the vaginal delivery group, leaving this latter group with a better outcome. However, even if morbidity and mortality in the CS-other group was added to that of the elective CS group to compensate for such a possible bias, still a difference of 1% (1.29% compared with 0.26%) of combined perinatal mortality / morbidity was present.

An argument against performing a planned CS in breech delivery could be the increased risk of pulmonary morbidity. Our data showed significantly more pulmonary morbidity after elective planned CS compared with planned vaginal delivery, especially wet lung (1.45% versus 0.87%). This difference was due to elective CS, performed at 37 and 38 weeks of gestation. Such findings have been published before.<sup>7-10</sup> They do not plea against a planned CS as such, but against performing a planned CS at too early gestational age.

Also other parameters of morbidity which are not so clearly associated with impairment in later life, such as hyperbilirubinaemia and need of resuscitation, occurred significantly more often in the planned vaginal delivery group as compared to the elective planned CS group. It might be speculated that hyperbilirubinaemia occurs more often after vaginal delivery because of more extensive bruising.

Fractures were more common after vaginal delivery, but the severity of fractures was greater after elective CS. Femur and humerus fractures may easily lead to severe haemorrhage and more serious neonatal problems. Not so much the mode of delivery but the performance of obstetric manoeuvres are thought to be common risk factors.<sup>11</sup>

There are several studies on the predictive value of the 5-minute Apgar score. Some studies provide evidence that a 5-minute Apgar score of less than 7 is already associated with neurological impairment in later life. The negative predictive value of a 5-minute Apgar score of less than 4 is quite unanimously claimed. In our study a significant 17-fold difference in 5-minute AS < 4 was found between the planned vaginal group and the planned CS group.

Outcome after vaginal delivery of breech infants was poorer than that of the other modes of delivery for all fetal weight categories. Poorest outcome occurred in infants weighing < 2500g and our data suggests that particularly a small-for-date breech infant has an

increased risk of mortality / morbidity, when delivered vaginally. Others have found impaired neurological outcome at 2 years of age in case of vaginal breech delivery and a birth weight of  $\geq 3500 \text{ g}$ , but we could not confirm that.

Our findings contrast with those of a similar study in part of France and Belgium<sup>19</sup>, including 8105 term breeches, over a one year period in 2001-2002. In that study no difference in perinatal outcome was found between VTOL and planned CS. However, it is difficult to compare the results of the two studies, because in the French / Belgian study congenital malformations were not excluded (present in 26% of infants who died or had severe morbidity), because obstetric complications were present in the planned CS group (e.g. fetal condition, maternal disease) and because allocation of cases of fetal death to the two subgroups remains unclear to us. Finally, the major part of severe morbidity in their study consisted of prolonged ventilation and / or parenteral or tubal feeding. The latter complications may have been induced by a too early elective CS. Alternatively, differences in neonatal policies could explain differences in ventilatory support. We would like to emphasize, that in our study the incidences of IRDS and pneumothorax were similar in the CS and VTOL groups. Even when these diseases would have been added to 'severe neonatal morbidity' the differences between the CS and VTOL groups would remain the same. Since 'wet lung' is a self-limiting disease with mostly a duration of less than 24 hours, we do not consider this serious neonatal morbidity. Parenteral or tubal feeding is always necessary when a neonate is intubated, but in the French / Belgian study it was considered as a separate expression of neonatal morbidity, which is not justified. Data on low Apgar score and trauma was almost the same as in our study.

In conclusion, elective CS in case of term breech is associated with a one percent lower incidence of mortality and newborn severe morbidity as compared to VTOL. This figure has to be weighed against an increased risk of maternal morbidity and mortality due to the caesarean section and an increased maternal and fetal risk in subsequent pregnancies, <sup>20,21</sup> especially uterine rupture <sup>22-26</sup> and placental invasion of the uterine scar during subsequent pregnancies, <sup>27-30</sup> possibly resulting in the hazards of emergency peripartum hysterectomy. <sup>31-34</sup>

Earlier we have shown that for every 10 infants 'saved' by an elective CS because of breech presentation, in The Netherlands, one infant will die during a subsequent pregnancy due to an uterine rupture.<sup>35</sup>

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# 5

# Why did the Term Breech Trial have such strong influence? A survey among 100 obstetric departments

Christine C.Th. Rietberg
Marjan Faber
Hein W. Bruinse
Richard Grol
Gerard H.A. Visser

#### INTRODUCTION

Changes in medical practice do not usually take place easily. Many examples exist of the difficulties encountered in implementing changes and improvements in patient care practices and it usually takes different approaches and much time to implement new or valuable insights, procedures, programmes and techniques.

Research has shown that clinicians are eager to find scientific support for decisions in clinical practice, but find it difficult to get good access to literature.<sup>1-3</sup> Therefore it takes often a long time and lots of effort to implement research results.

The opposite occurred in The Netherlands in the year 2000, following the publication of the results of a prospective randomised controlled trial on the best mode of delivery of term infants in breech position. Within two months there was a steep, swift and consistent change in obstetric policy with respect to term breech delivery (see Chapter 3).

In this chapter we describe the results of a questionnaire survey among all 100 obstetric departments in The Netherlands in order to find out what exactly caused this abrupt change and what influences were important.

# **History**

In The Netherlands a steady policy on term breech deliveries had been in effect for years. Until 2000 approximately half of the breech deliveries resulted in a caesarean section (CS). The percentage of CS had somewhat risen in the previous years (Figure 1), but overall the behaviour of obstetricians was steady. The policy was based on a long history of common practical sense. A guideline by the Dutch Society of Obstetrics and Gynaecology (NVOG) in 1998 formalised the policy.<sup>4</sup> This guideline stated that 'in case of a breech position the routine performance of a caesarean section is undesirable if the fetal position is the only indication'.

In October 2000 the results of the Term Breech Trial (TBT)<sup>5</sup> were published by the Term Breech Trial Collaborative Group. In this trial patients were randomised either for a vaginal trial of labour or planned CS. It was concluded that a policy of planned CS was substantially better for the singleton fetus in breech position at term, with no associated higher risk of serious problems for the mother.

In November 2000, shortly after publication of the TBT, the Dutch Society of Obstetrics and Gynaecology issued a statement in a letter to all Dutch gynaecologists and residents, advising that 'the better neonatal results of the Term Breech Trial should be discussed when counselling the pregnant woman'. In the letter a revision of the guideline was announced, which was indeed published in April 2001.<sup>6</sup> So, from November onwards, a CS only because of breech position was no longer banned.

Questionnaire survey 53

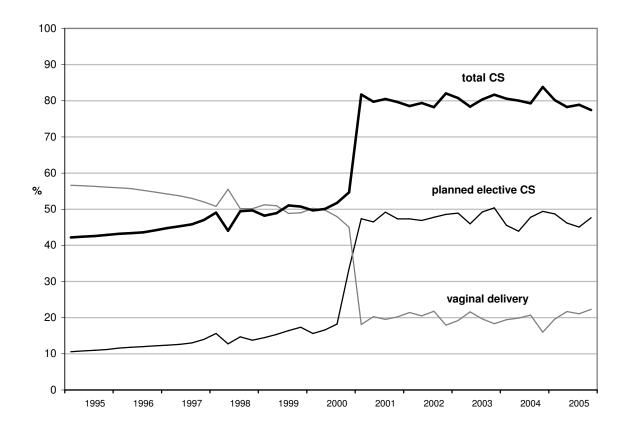


Figure 1. Mode of delivery (%) in the years until publication of the Term Breech Trial in 2000 and thereafter.

The publication of the TBT led to many press articles and the conclusions of the study were discussed in several radio and television programs.

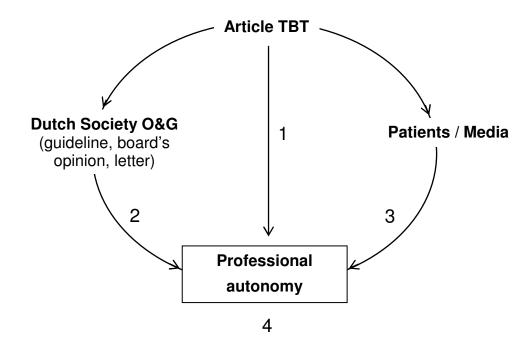
Within two months after publication of the TBT the CS rate in case of breech position increased from 50% to 80%, to remain stable thereafter (Figure 1). The rise was mainly caused by an increased rate of planned CS, performed only because of breech presentation. This effect of the TBT has been described previously,<sup>7,8,9</sup> as have studies about the effect on neonatal mortality and morbidity.<sup>7</sup>

# **METHODS**

## Questionnaire

In order to explain the abrupt and tremendous change in clinical practice in more detail, we conducted a survey amongst all obstetric departments in The Netherlands. Our questions focused on the factors that had played a role in the change of behaviour of the obstetrician.

Figure 2. Theoretical model which formed the basis for the questionnaire.



As a guidance we formulated a simple theoretical model (Figure 2), which recognises four influences:

- 1. the scientific influence of the article itself.
- 2. the influence of the Dutch Society of Obstetrics & Gynaecology (letter, revised guideline).
- 3. the influence of the patient, family and the media.
- 4. the influence of the obstetrician's professional autonomy.

If influence from the Dutch Society on the change in policy played an important role, it must have been through their letter of November 2000, since the revised guideline was issued in April 2001, after the change in obstetric policy had already taken place. The revision could therefore not have played a direct role, but it could have been important in maintaining the newly achieved balance, and its possible importance is expressed in today's practice.

The underlying idea of influence 3 from the model is that patients can exert a large influence on the doctor's decision to perform a CS and that patients themselves are probably influenced by their family and / or the media.

With respect to the obstetrician's professional autonomy, it might well be possible that the TBT formed a welcome defence for those obstetricians who did not favour a vaginal breech delivery anyway. Additionally, there is a hypothetical possibility that the

Questionnaire survey 55

obstetrician directs the patient towards a decision by means of specific ways of counselling. The doctor who favours a vaginal delivery may counsel differently than the doctor who favours a planned caesarean section.

The questions in the questionnaire were derived from this model (see appendix). The first question examines whether policies are mostly uniform or divergent within the departments. Questions 2-5 investigate the influence of the TBT. In question 6 and 7 the influence of the Dutch Society is tested. Questions 8 and 9 and 11-13 deal with the influence of the patient and/or media. Questions 10 and 14-16 investigate the importance of the professional autonomy. Question 17 tests the own insights of the department into the different influences on the changed behaviour with a scoring of the various influences and questions 18 and 19 aim to correlate the changes in CS rate per department with the given answers.

# **Participants**

There are 99 obstetric departments in The Netherlands: 8 university teaching hospitals, 36 teaching hospitals and 55 non-teaching hospitals. Each department was asked to fill out the questionnaire as a team. The response was 86% (all university teaching hospitals; 34 teaching hospitals and 43 non-teaching hospitals). Three departments (non-teaching hospitals) gave their response after the closing date of the survey. This resulted in a total of 82 questionnaires for analysis.

# **Analysis**

The analysis of the questionnaires was done in two steps. First, the distribution of the answers of the departments was determined. Subsequently, we compared the percentage of planned caesarean section (pCS%) for term breech in 1999 (the year before the TBT) and 2004 (paired t-test). The answers to the questions were related to the pCS% of 2004. Based on the distribution of the answers on the questions, the contribution of the four influences of our model could be investigated in regression models. In these models the pCS% of 2004 as the dependent variable and the pCS% of 1999, together with the answer-distribution as independent variables, were investigated. To investigate the relative importance of various influences, multi-variate regression models were used. Two departments could not give CS percentages due to incomplete registration and were not included in the correlation analyses. All departments gave their consent on using the department-specific percentages.

## **RESULTS AND INTERPRETATIONS**

In all but two of the departments the pCS% increased between 1999 and 2004. Figure 3 shows the pCS% in 1999 *vs* 2004 for term breech delivery and for term vertex. The average pCS% for breech was 26% in 1999 and had more than doubled to 61% in 2004, with an average increase of 35%. For vertex position the percentages for planned CS were 4.8% and 6.1%, respectively (increase of 1.2%).

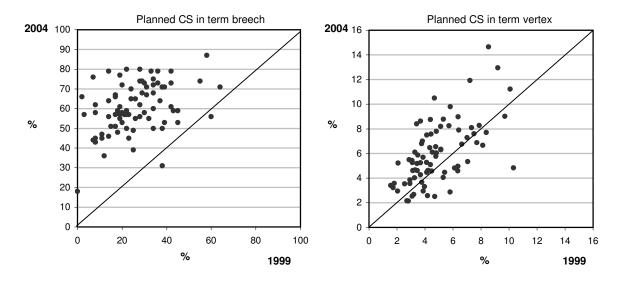


Figure 3. Difference in planned caesarean section percentage in 1999 and 2004 for term breech and term vertex.

In the following, results are presented per question (Q). In table 1 percentages of pCS in 1999 and 2004 are summarised and the effect is described, expressed as the increase in pCS% that is caused by the factor that was tested, with 95% confidence intervals (95%-CI) between brackets.

#### General

Q1: 73% of departments reported that at present they have agreement on the policy of planned caesarean section in case of a term breech delivery, in 20% the team of gynaecologists incidentally disagreed and in 7% of departments there was a fundamental disagreement between gynaecologists about the management of these cases.

### Influence of the TBT

Q2: 88% of departments reported that they were informed on the results of the TBT by reading the article, 68% by the letter from the Dutch Society (more than one answer was possible). Half of the departments were informed through a presentation at the

Questionnaire survey 57

National Symposium (held twice a year) and in 35% the conclusions of the article were brought up by one of the colleagues.

- Q3: Discussions about a new team policy led to mutual agreements in 71% of the departments, while in 29% no team policy was formulated (policy was left to the individual obstetrician). Departments leaving the policy to the individual obstetrician had an above-average pCS% in 1999. In both groups the CS rate increased, with no significant difference in increase between these groups.
- Q4: 64% of departments found the TBT-study either not scientifically well founded or not applicable to the Dutch situation, while 36% of responders found the study scientifically sound and applicable. There was no difference between these two groups in pCS% in 1999 nor in the rise of pCS%.
- Q5: 94% of departments responded that there had been a large or moderately large influence of the TBT on the policy of pCS in term breech delivery. Comparing the answers of these responders with those of the departments that reported little influence of the TBT, the latter group had a significant smaller increase in pCS% from 25% in 1999 to 46% in 2004 than the other group. However, the group of responders reporting little influence of the TBT was only small (5 departments) and might therefore not be a representative sample.

# Influence of the Dutch Society of Obstetrics and Gynaecology

- Q6: 84% of departments reported large or moderately large pressure from the Dutch Society of O&G through their letter to all gynaecologists about counselling the patient after publication of the TBT, while 16% of departments felt little influence. When comparing the change in pCS% no significant difference was seen between these groups.
- Q7: 70% also experienced a large or moderately large influence through the revised guideline of the Dutch Society, 26% felt little and 4% no influence. The departments that felt little or no influence of the revised guideline had an above-average pCS% in 1999 and showed a smaller increase as compared to departments experiencing a (moderately) large influence, although this difference was not significant.

# Influence of the patient

Q8: After the TBT, 82% of departments reported a large change in the wishes and preferences of the patients towards a planned CS in term breech. Striking is that the

18% of departments that noticed moderate or little change in the patients' wishes had a significantly smaller increase in pCS% after the TBT than the departments noticing a large change. This indicates that if the perceived influence of patients is large, the change in clinical practice is higher. In fact, almost 10% of the 37% increase in pCS% appears to be due to this patient influence (95%-CI 3.9-16.0%).

- Q9: In 86% of departments it occurs often or regularly that the patient refuses a vaginal delivery, in a situation assessed as favourable for vaginal delivery by the obstetrician. The 14% of departments that reported that patients seldom refuse a trial of labour, had an above-average pCS% in 1999 (not significant), indicating that a vaginal delivery was advised less frequently. This could well explain why these departments report fewer refusing patients.
- Q12:In 33% of departments it was reported that the doctor's advice with respect to the mode of delivery in term breech is followed to a great extent, while 67% of departments report that doctors advice is only followed to some or little extent. The departments in which the advice was followed to a great extent had a larger increase of pCS% of 40% as compared to 33% among the other departments [effect = 6.0% (95%-CI 0.8-11.1%)].

# Counselling and providing of information: doctor's autonomy

- Q14:99% of departments reported that the patient is provided with information through conversation and counselling in the consulting room. 78% of departments also hand out a brochure from the Dutch Society about breech delivery. Another 11% provide information through a nurse / midwife or other caregivers (more than one answer possible).
- Q10:When the patient persists in her wish for a caesarean section while the doctor's assessment is in favour of a vaginal delivery, the large majority (88%) of departments state that they perform a pCS without further discussion. Only a small proportion of departments proceed in counselling and convincing towards vaginal delivery. No department refuses a CS or refers to another hospital.
- Q15:In counselling the patient about perinatal risks, 15% of departments state that they specifically mention an increased risk of perinatal mortality in case of vaginal delivery, 27% mention an increased risk of neonatal trauma, but do not mention mortality and 57% mention the increased perinatal risk more in general (i.e. 'there is more risk for the baby with a vaginal delivery').

Questionnaire survey 59

Q16:In counselling the patient about maternal risks related to CS, 70% state that they mention specific future maternal risks in subsequent pregnancies, like uterine rupture, placenta increta and emergency hysterectomy. Of these, more than 80% (57% of total) also mention direct risks of complications when undergoing CS. 27% of departments state that they do not counsel specifically and just mention in more general terms that future pregnancies carry more risks for the mother after previous CS. Of the latter group more than half (15% of total) do mention direct risks of complications. In conclusion, 97% of departments inform to some extent about increased future maternal risks in subsequent pregnancies.

# Influence of media and family

Q11-12: 37% of departments reported that the influence of the media on the patients' choice in the mode of delivery is large, while 43% thought it was moderate and 20% of little influence. If media influence is considered to be large, 75% of patients do not follow doctor's advice, while if media influence is considered moderate or little, 61% still do not follow doctor's advice, in other words the media influence does not seem large.

Q12-13: 51% of departments reported that the influence of patients' social context (i.e. family, friends) seems large. 42% thought that this influence is moderate and 7% thought it is little. If family's influence is considered to be large, 85% of patients do not follow doctor's advice, while if family's influence is considered moderate, 48% do not follow doctor's advice.

# Assessment of different influences by the departments

Q17:In the last question the department was asked to rate the different influences in a score from 1 (no influence) to 10 (highest possible influence). The mean values (with standard deviation between brackets) are as follows:

•	the article about the TBT	7.4 (± 2.0)
•	the letter of the board of the Dutch Society	7.4 (± 2.3)
•	the revised guideline based on the TBT	6.7 (± 2.6)
•	pressure from the patient	6.4 (± 2.5)
•	publications in the media	4.9 (± 2.6)
•	negative experiences in the department relating to	3.9 (± 2.4)
	vaginal breech delivery	

Table 1. Results of the survey questionnaire. pCS% = planned caesarean section percentage. The effect is expressed as the percentage of increase that is caused by de factor that was tested. 95% Confidence intervals are given between brackets.

			N	%	· %	pCS % 2004	Δ	Effect on pCS% 2004 (95%-CI)
1	How much agreement within	large amount of agreement	60	73	25	62	37	6.8 (-2.7 to 16.4)
	the team about policy on	incidental disagreement	16	20	25	56	31	0.6 (-7.5 to 0.3)
	term breech delivery	fundamental disagreement <sup>#</sup>	6	7	37	61	24	
		through the article	72	88				
2	How did department hear	from colleagues	29	35		NA		
	about the TBT (more than 1 answer possible)	through letter of board Dutch Society	56	68		INA		
		through presentation	41	50				
		nothing <sup>##</sup>	1	1	38	31	-7	
3	What did department do with conclusions of the TBT	policy left to individual obstetrician#	23	28	30	62	32	0.4 (-5.3 to 6.0)
	CONCIUSIONS OF THE TEN	mutual agreements about team policy	58	71	24	60	36	
4	General assessment about	scientifically good	29	36	28	63	35	3.3 (-2.2 to 8.8)
	conclusions TBT	not good / not applicable to NL#	51	64	25	59	34	
5	Influence TBT on policy	large / moderately large	75	94	26	61	35	14.8 (4.5 to 25.2)
	term breech delivery	small <sup>#</sup>	5	6	25	46	21	
6	Influence statement of	large / moderately large	68	84	26	60	34	-1.3 (-5.7 to 6.1)
	board of Society O&G	small <sup>#</sup>	13	16	27	62	35	
7	Influence revised guideline	large / moderately large	57	70	24	61	37	3.2 (-2.6 to 9.1)
	on policy	small <sup>#</sup>	24	30	30	60	30	,
8	Which change in patients'	large change	67	82	25	63	37	9.9 (3.9 to 16.0)
-	wishes noticed after TBT	moderate / little change#	15	18	30	54	25	
9	How often refuses patient	very often / often	70	86	25	60	35	-0.8 (-8.5 to 7.0)
	when you consider vaginal delivery safe	seldom / never#	11	14	30	63	33	
10	What do you do if vaginal	caesarean section	72	88	27	61	35	3.1 (-4.8 to 11.1)
	delivery is favourable but patient wants CS	repeated counselling, finally CS#	10	12	21	56	35	
11	What is the assessed	large	30	37	26	61	35	1.2 (-4.3 to 6.6)
	influence of the media	moderate / little <sup>#</sup>	52	63	26	60	34	
12	How strongly does patient follow your advice about	strong	26	33	25	65	40	6.0 (0.8 to 11.1)
	route of delivery	moderate / little#	53	67	26	59	33	
13	How strong is the perceived	strong	42	51	26	61	35	0.3 (-4.9 to 5.6)
	influence of the family	moderate / little <sup>#</sup>	40	49	26	60	34	
15	Counselling about perinatal	higher perinatal mortality	12	15				
	risk	higher perinatal trauma	29	35		NA		
		less specific	53	65	•			
16	Counselling about maternal	specific on maternal risks now / later	71	87		NA		
	risk	less specific	35	43		11/7		

<sup>\*\*</sup> serves as reference category in regression analysis\*\*\* not included in the regression analysis

Questionnaire survey 61

# Multi-variate analyses

Out of all the factors tested, ony three factors appeared to have a significant contribution to the increase in pCS: the influence that the TBT had on policy (Q5), a change in patients' wishes (Q8) and the degree to which patients follow the advice (Q12). In a multivariate regression model all three factors had an independent, significant effect. A positive answer on Q5, i.e. indicating that the TBT had a large or moderately large influence on policy, was the strongest factor.

# **DISCUSSION**

For many years the obstetric standard in The Netherlands for breech had been a vaginal delivery, and when careful selection was performed this was considered safe. This was based on years of experience and on the guidelines of the Dutch Society, that held many advices and suggestions (for instance caution with labour augmentation, no breech extraction for obstructed labour, limited time of second stage, no expected feto-pelvic disproportion, no hyperextension of the fetal head, no previous history of difficult vaginal labour). This resulted in a low planned CS percentage as compared to other countries.

It is said that clinicians often do not act rationally, but decide on the basis of previous experiences and contextual information. However, only one randomised trial like the TBT was needed to cause an abrupt and tremendous change in clinical practice, despite the long history of vaginal breech, the wide expertise and experience and a well-developed guideline. One can only conclude that other influences besides the scientific merit of this trial must have been in force.

All over the world the TBT has had its impact, but an increase in planned CS rate of 35% in a two months time period, as happened in The Netherlands, is extreme. In part this is due to the initial low percentage, which allowed for a large increase.

The Canadian research institute which conducted the TBT reported in 2003 that 92.5% of collaborating centres, which responded to a questionnaire, stated that clinical practice had changed to planned CS for most or all term breech babies. Large institutions like the American College of Obstetricians and Gynecologists endorsed the recommendations of the TBT and revised their guideline. In Australia and New Zealand prior to the TBT, 72% of obstetricians routinely offered a vaginal breech birth for uncomplicated singleton breech pregnancies, while after the TBT this rate declined to 20%. In Sweden the CS rate for singleton term breech increased from 75.3% in 1999 to 86.0% in 2001. In Belgium the CS% for breech was 75.4% in 1999 and increased to 84.6% in 2001. So, the results of the TBT also had an effect in many other countries.

The following observations can be condensed from the questionnaire answers and the regression analysis:

- 1. Scientific influence of the TBT article itself. After regression analysis the effect of the TBT appears to be a significant factor (14.8% (95%-Cl 4.5-25.2%) of the 35% change in pCS can be attributed to the influence of the TBT). In almost all departments an increase in pCS% was seen and therefore it seems logical that most departments will answer that they perceived a large influence from the TBT. Consequently, in the questionnaire 94% of departments stated that they perceive that the TBT had (moderately) large influence on the policy of pCS in term breech delivery. Nevertheless, 64% of departments state that they either do not find the article scientifically well founded or do not find it applicable to the Dutch situation. From this discrepancy we conclude that other influences must have played a significant role in changing practice.
- 2. Influence of the Dutch Society of Obstetrics and Gynaecology. The board of the Dutch Society of Obstetrics and Gynaecology chose a firm position by sending a letter stating that 'the better neonatal results of the Term Breech Trial had to be discussed in the consulting room'. With such a statement from a normative authority the obstetrician was formally obliged to follow its advise. This is likely to have had a considerable effect in all cases in which the obstetrician favoured a vaginal delivery, because discussing the results of the TBT could lead to pressure from the patient towards a CS. Furthermore, the removal of the statement from the guideline that 'routine performance of a caesarean section only because of the fetal position is undesirable', freed the way to liberally perform caesarean sections for all obstetricians, in particular for those who were adverse of attending vaginal delivery because of fears, stress or negative experiences. From the regression analysis it can not be concluded that the Dutch Society largely influenced the change in practice. However, 85% of departments stated that its influence had been large and on the scoring list this influence was scored second most important. The Dutch Society had a direct influence on the obstetrician by freeing the way to liberally perform CS's. In addition, it had an indirect influence on the obstetrician, because it enhanced the influence of the patient by obliging the obstetrician to discuss TBT-results and therewith sharing decision-making with the patient.
- 3. The patient and her family exert a large influence on the doctor's decision to perform a caesarean section. For the pregnant woman, with a safe delivery of

her unborn child foremost in her mind, it is hard to make a balanced judgement about the best mode of delivery, taking all risks into account for the index pregnancy and for future pregnancies and offspring. Hearing about the better results of the TBT in case of an elective CS is likely to influence her choice.

The influence of the patient is confirmed by different correlations we found. 82% of departments noticed a large change in the wishes and preferences of the patient towards pCS. If the perceived influence of patients was considered larger, the change in clinical practice was greater. Ten percent of total increase in pCS% can be explained by the patients' influence. Furthermore, if the family's influence is rated as large, the majority of departments feel that patients do not adopt the doctor's advice, whereas if the family's influence is rated as moderate, half of the patients do. The fact that clinicians consider the media and women responsible for the rising trend of CS's for term breech deliveries has been described before in a survey among obstetricians in the UK.<sup>15</sup>

4. **Influence of the professional autonomy.** This is not easy to investigate, since the questionnaire was not sent to individual obstetricians but to obstetric departments and one member was asked to formulate a collective answer with and on behalf of the team. One might say that the TBT was a welcome solution for those who favoured a CS. We have no data to support this. Others, however, have expressed opinions in that direction, e.g. Glezerman, how has stated: "The recommendations of the TBT were not only awaited anxiously by obstetricians of mainly Western countries but also almost gratefully accepted. It is much easier to plan an abdominal delivery than a vaginal delivery and it requires less expertise to do so. Moreover, in the current medicolegal environment, in which litigation for a performed caesarean section is a rare event but vaginal delivery carries increased risks for litigation, obstetricians easily can be convinced not to take this risk."

69% of departments emphasized the importance of the revision of the guidelines. Since this revision was in fact the removal of a block to perform a CS, we conclude that the underlying considerations about risk must indeed be important. However, we could not find a general correlation between the answer to the question about the importance of guideline change and CS in 1999, 2004 or the difference between them. This may well indicate that the feelings expressed by Glezerman are indeed widespread.

Another influence concerning the professional autonomy could be the assumption that the obstetrician directs the patient towards a decision by means of specific ways of counselling. Different ways of counselling the patient about perinatal and

maternal risks appear not to be correlated to different intervention rates. Therefore, the hypothesis that obstetricians who preferably perform a caesarean section are more specific in mentioning the increased perinatal risks of vaginal delivery and obstetricians who preferably counsel towards vaginal delivery more specifically mention maternal / future risks of the caesarean section can not be confirmed. Still, the widespread differences in pCS rates amongst departments suggest that the doctor's own policy remains of great importance.

Furthermore, a significant effect is found in question 12 in the regression analysis, in which 33% of departments state that the patient strongly follows the doctor's advice. The fact that these departments have a greater increase in pCS% than the departments that feel that the patient does not follow the doctor's advice might seem strange. However, this could be explained by the following: departments with a preference for CS will more often advise their patients to have a CS than departments that favour a vaginal delivery. Many patients prefer a CS in case of breech. Therefore, departments preferring a CS will encounter more patients who are very willing to follow this advice. These departments will give the answer to question 12 that the patient strongly follows their advice and will end with a higher increase in pCS%.

Finally, by analysing the questionnaire some additional considerations can be made:

- 1. mutual agreement within the team on policy of breech delivery leads to fewer interventions (as can be concluded from the results from question 1 and 3).
- 2. changing the guideline was only of influence to departments in which the guideline had already been implemented in 1999.
- 3. the family's influence seems more important than that of the media.

### CONCLUSION

The questionnaire has provided valuable data about the perceptions of participating departments. Since they represent more than 80% of all departments, this data is likely to be relevant. Furthermore, because of a well developed perinatal registry and the willingness of the obstetricians to reveal their department intervention rates, the questionnaire provided us with pre- and post-TBT caesarean section percentages. These represent measured rather than perceived information.

Interesting discrepancies were found both between different questionnaire answers and between these answers and the CS percentages. For instance, only one third of departments judge that the TBT was sound / applicable to The Netherlands and yet virtually all departments report that the TBT's influence on its policy has been major. Moreover, whether the perceived influence of the Dutch Society on a department's policy was considered large or small, this does not show in differences in increase of CS percentage. These discrepancies should not be considered as contradictory. Rather, they give directions as to what really happened, which is in our opinion:

- The TBT has caused it all: Without it there would have been no dramatic change.
- The media picked up the implications with an unprecedented eagerness and in a
  way that is not seen often when randomised trials reveal important medical
  insights. And the media translated the finding in simple terms: a CS is better for the
  child in breech.
- The Dutch Society made two major contributions: it removed an obstacle for CS in uncomplicated breech and it forced obstetricians to discuss the TBT results with patients.
- Influenced by the opinionated patient herself, obstetricians shifted their policy about breech delivery to the safer end of medical practice, both with respect to the risk of complications for the baby as to the risk of litigation of malpractice. This patient influence, directed by strong media attention and amplified by the Dutch Society's stimulation to communicate trial-results with the patient, seems to be the most important factor as a basis for the change in medical practice in case of term breech.

### **APPENDIX**

### Questionnaire

1 To which amount is there agreement within your team on the policy of planned caesarean section in case of a term breech delivery

- a. Large amount of agreement of opinion
- b. Incidental disagreement of opinion
- c. Fundamental disagreement of opinion
- 2 In which way did your department hear about the conclusions of the Term Breech Trial (end 2000) (more than one answer possible)
  - a. the TBT-article was read
  - b. the conclusions of the article were brought up by one of the colleagues
  - c. through the letter of the board of the Dutch Society of Obstetrics & Gynaecology
  - d. heard on a presentation
  - e. other, namely
- 3 What did your department do with the conclusions of the Term Breech Trial
  - a. nothing
  - b. they were discussed within the team, but the decision and policy were left to the individual obstetrician
  - c. mutual agreements were met on the policy to be followed
- 4 What is the general assessment about the conclusions of the TBT
  - a. scientifically soundly based
  - b. scientifically not soundly based
  - c. not applicable to the Dutch situation
- 5 Which influence did the TBT have on the policy in your department on caesarean sections in case of a term breech position
  - a. large
  - b. moderately large
  - c. little (please answer question 5a)
- **5a** If the TBT had little influence on the policy in your department, what were the reasons for this (you may give more than one answer)
  - a. negative criticism on the TBT in the department
  - b. not convinced about the conclusions
  - c. doubts as to whether patients will accept the consequences of the conclusions
  - d. doubts about the practical applicability of the results
  - e. financial or structural restrictions in your hospital
  - f. other
- 6 How large was the influence of the attitude of the board of the Dutch Society of Obstetrics & Gynaecology towards the term breech delivery on the policy in your department (letter following the TBT-publication in November 2000, referring to the way counselling of the pregnant patient with a fetus in breech position had to be done)
  - a. large
  - b. moderate
  - c. little
  - d. no influence
- 7 How large was the influence of the revised guideline of the Dutch Society on 'breech delivery' (revised in July 2001) after the TBT on the policy in your department
  - a. large
  - b. moderate
  - c. little
  - d. no influence

- **8** To what amount did you notice a change in the wishes / preferences of patients towards a caesarean section after the publication of the TBT
  - a. a large change
  - b. a moderate change
  - c. a little change
  - d. no change
- 9 How often does it occur that you think a vaginal delivery is safe to accept, but the patient refuses
  - a. very often
  - b. regularly
  - c. seldom
  - d. never
- **10** What is your policy when a patient persists in her wish to have a caesarean section, whereas you find the situation favourable for a vaginal delivery
  - a. I perform a caesarean section
  - b. I proceed in counselling and convincing towards a vaginal delivery
  - c. I refuse, if necessary I refer her to a colleague
  - d. Other, namely.....
- 11 How large do you assess the influence of the press / media on the choice of the patient for the mode of delivery (with fetus in breech)
  - a. large
  - b. moderate
  - c. little
  - d. no influence
- 12 To what extent do patients follow your advice with respect to the mode of delivery (with fetus in breech)
  - a. to large extent
  - b. to some extent
  - c. to little extent
  - d. not
- 13 How large do you assess the influence of the social context (family, friends etc) to the wish of the patient with respect to the mode of delivery (with fetus in breech)
  - a. large
  - b. moderate
  - c. little
  - d. no influence
- 14 How do patients get their information on the risks for the mother and the baby in case of a vaginal delivery in contrast with a caesarean section for the term breech delivery (you may give more than one answer)
  - a. through conversation and counselling
  - b. through the brochure 'breech position' from the Dutch Society
  - c. through counselling by a nurse / midwife or other care taker
- 15 Which aspects about the risks for the baby do you mention in case of a vaginal delivery of a term baby in breech position
  - a. increased risk of mortality during labour
  - b. increased risk of perinatal trauma
  - c. more common: 'for the baby the risk is increased'
  - d. none of these
- **16** Which aspects about the risks for the mother do you mention in case of a planned caesarean section with a term baby in breech position
  - a. increased risk of direct maternal complications caused by the caesarean section
  - b. increased risk of uterine rupture in a future pregnancy / delivery
  - increased risk of other complications in a future pregnancy, such as placenta praevia / increta and hysterectomy
  - d. more common: 'in a future pregnancy there will be more risks for the mother'
  - e. none of these

17 Please give a rate about the effect on changes in policy within your department in case of a breech delivery (you can rate in a scale from 1 to 10; 10 = large influence)

a.	the article about the TBT	110
b.	the letter of the board of the Dutch Society	110
c.	the revised guideline based on the TBT	110
d.	pressure from the patient	110
e.	publications in the media	110
f.	negative experiences in your department towards a	110
	vaginal breech birth	

18 Would you please answer the following questions? This would give us insight in the increase in caesarean section per department for breech in comparison to vertex deliveries. This will answer the question whether the increase in caesarean sections in case of breech delivery shows a parallel and relationship with the increase in case of vertex. If answering gives rise to difficulties, you may skip this question.

What was the percentage of planned CS for term infants in breech in your department in 1999 and in 2004 (see instructions how to abstract this percentage from your Obstetric Registry)

1999 2004

**19** What was the percentage of planned CS for term infants in vertex position in your department in 1999 and in 2004

1999 2004 Questionnaire survey 69

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## 6

## There are more girls than boys in breech position

Christine C.Th. Rietberg
Patty M. Elferink-Stinkens
Gerard H.A. Visser

### Submitted

### **SUMMARY**

The male to female ratio at birth varies in different populations, but always a male preponderance is seen. At delivery approximately 51.5% of infants are boys and 48.5% are girls. However only very little is known about gender differences among fetuses born in breech position. We aimed to investigate the relationship between fetal gender and breech position. In a large retrospective observational study conducted in The Netherlands the incidence of breech deliveries in male and female fetuses in relation to gestational age and weight at birth was studied, using data derived from The Netherlands Perinatal Registry. Between 1995 and 2002 1.3 million singleton infants, of whom 70,125 were in breech position at delivery, with gestational age of 24 to 42 weeks, were studied. Multiple pregnancies were excluded.

It appeared that from 32 weeks of gestation onwards there were significantly more girls than boys in breech position at delivery. At 40 weeks only 43.4% of breeches were boys. Breech position at delivery was dependent on gestational age and weight at birth, but fetal sex appeared to be an independent variable. At term girls were delivered vaginally more frequently than boys. In conclusion, more girls than boys are in breech position at delivery from 32 weeks onwards. The aetiology is unknown, but may be related to differences in size and shape of the fetal pelvis or hips.

### INTRODUCTION

More boys are conceived than girls and at delivery approximately 51.5% of infants are boys and 48.5% are girls. Only very little is known about gender differences among fetuses born in breech position. In literature only a few studies mention a female preponderance among breech babies. These studies are small, including approximately 400 - 2400 breeches, and were not able to analyse gender differences according to gestational age and birth weight.

We have studied the girl-to-boy-ratio in detail among breech deliveries nationwide, using the data of The Netherlands Perinatal Registry and correcting for gestational age and weight at delivery. This study includes the period 1995 – 2002, during which approximately 1.3 million infants were born, of whom over 70 thousand in breech position.

### **METHODS**

In The Netherlands, data on pregnancy and delivery is gathered in national databases, which include data from 95%-99% of all hospital deliveries in secondary (high risk) care (obstetricians) and about 90% of primary care (low risk hospital and home) deliveries (midwives). Breech deliveries are restricted to secondary care, so the former data set has enabled us to determine the male to female ratio of infants delivered in breech position. In order to present breech position as a percentage of all deliveries both data sets were combined. Multiple pregnancies were excluded.

We used a logistic regression model to calculate the correlation between breech position and gestational age, birth weight and gender. A chi-square test was used to determine significance of differences. The period 1995 - 2002 was studied. Gestational age is expressed as whole weeks.

### **RESULTS**

In the eight-year-study-period 1,357,129 singleton children were included in the registry with a gestational age ranging from 24 - 42 weeks. At early gestation the difference in delivery rate between boys and girls was greater than at term: before 37 weeks 55.5 % of infants born were boys and thereafter 50.9 %. There were 70,125 breech deliveries, 46.6% of which were boys and 53.4% girls. These percentages were consistent over the years.

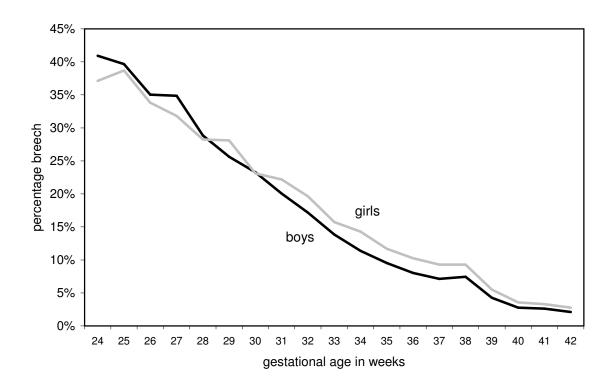


Figure 1. Percentage of girls and boys who were born in breech position from 24 to 42 weeks of gestation. Data derived from primary and secondary care data sets; 1995 – 2002.

The incidence of breech position decreased linearly with gestation from about 40% in deliveries at 24 weeks to 3% at term (Figure 1). Only at 37 and 38 weeks the incidence of breech deliveries did not change and at 39 weeks a steeper decrease in incidence was seen. From 32 weeks onwards, girls were consistently and significantly more often in breech position than boys (Figure 1 and Table 1).

The incidence of breech position and breech delivery is related to gestational age and therefore also to fetal weight. Girls weigh less than boys, also in case of breech position (data not shown), which could explain the difference in breech position found at term. We have investigated this by standardising for gestational age and plotting the percentages of breech delivery in boys and girls for the different weight categories. Data is shown for the 362,061 deliveries that took place at 40 weeks of gestation (40 weeks to 40 weeks + 6 days) (Figure 2). This includes 11,628 breech deliveries of which only 43.3% were boys. There was a higher percentage of breech position in the lower weight categories. The percentage of breech position was consistently higher for girls than boys for all weight categories until 4500g, with larger differences at lower weights. The findings in the surrounding weeks were similar (data not shown).

Table 1. Percentage of boys and girls born in breech position per week of gestation, with odds ratios for the girl-to-boy difference and 95% confidence intervals. Significant findings are presented in bold characters.

gestation	girl	boy	OR	95%-CI
24	37.1%	40.9%	0.85	0.65 - 1.12
25	38.7%	39.7%	0.96	0.74 - 1.25
26	33.8%	35.0%	0.95	0.75 - 1.20
27	31.8%	34.9%	0.87	0.70 - 1.09
28	28.2%	28.8%	0.97	0.79 - 1.20
29	28.1%	25.6%	1.13	0.93 - 1.38
30	23.1%	23.3%	0.99	0.82 - 1.20
31	22.2%	20.1%	1.14	0.95 - 1.35
32	19.6%	17.2%	1.18	1.01 - 1.38
33	15.7%	13.8%	1.16	1.01 - 1.33
34	14.3%	11.4%	1.30	1.16 - 1.45
35	11.7%	9.5%	1.26	1.14 - 1.38
36	10.3%	8.0%	1.31	1.22 - 1.41
37	9.3%	7.1%	1.33	1.27 - 1.40
38	9.3%	7.5%	1.27	1.23 - 1.31
39	5.5%	4.3%	1.31	1.27 - 1.35
40	3.6%	2.8%	1.30	1.25 - 1.34
41	3.3%	2.6%	1.27	1.21 - 1.34
42	2.8%	2.1%	1.32	1.19 - 1.45
Total	5.7%	4.7%	1.22	1.20 - 1.24

Table 2. Logistic regression model: weight, gestational age and gender in relation to breech position.

	Odds ratios	95% Confidence intervals
Weight per 100g	0.948	0.946 - 0.949
Gestational age per week	0.896	0.892 - 0.900
Gender: girls versus boys	1.186	1.167 - 1.204

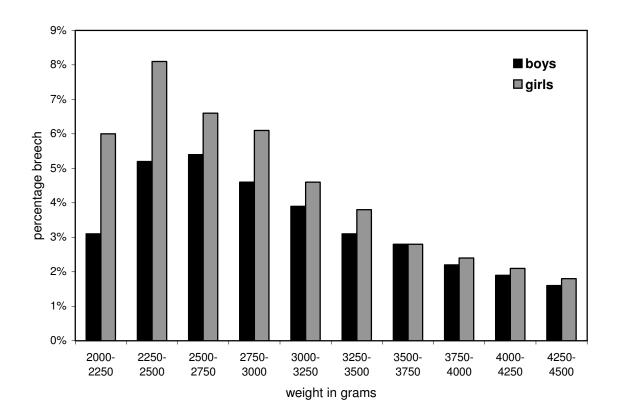


Figure 2. Percentage of girls and boys for the different weight categories from 2000 - 4500g, who were born in breech position at 40 weeks of gestation. Data derived from primary and secondary care data sets; 1995 - 2002.

Logistic regression showed that weight, gestational age and gender were all significant factors with respect to breech position (Table 2).

When looking at gender differences in relation to mode of delivery, there appeared to be a higher incidence of caesarean section (CS) among term boys in breech position as compared to girls (50.9 and 45.0% respectively), mostly as a result of a higher incidence of CS during labour (27.0 and 23.5%, respectively). Consequently more term girls than boys in breech position were born vaginally (54.3 and 48.5%, respectively). This phenomenon was especially noticeable before the publication of the Term Breech Trial in October 2000.<sup>8</sup> After this publication the overall CS rate in The Netherlands increased from approximately 50% to 80%.<sup>9</sup> However, also thereafter still more girls than boys in breech position were born vaginally (20.5% and 18.4%, respectively). Figure 3 shows the incidences of planned elective CS, planned CS because of other reasons than the breech position, emergency CS and vaginal delivery per week of gestational age.

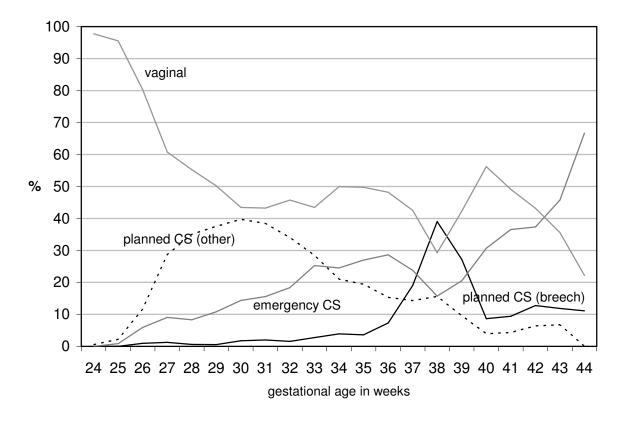


Figure 3. Breech positioned babies born between 1995 – 2002. Mode of delivery per week of gestation, for CS (elective, emergency, other indications) and vaginal delivery (in percentages).

### DISCUSSION

Our data shows that from 32 weeks of gestation onwards there are more girls than boys in breech position, despite the overall dominance of boys. Breech position at delivery is dependent on gestational age and on birth weight corrected for gestation, but fetal sex appears to be an independent variable. Factors that may play a role include differences in size and shape of the fetal pelvis or hips. Our findings confirm those of small series in unselected populations, including term and preterm deliveries, in which 51% tot 55% of all singletons in breech position at birth were found to be girls as can be seen in Table 3. None of these studies were able to focus on the relationship between gender, gestational age and birth weight, due to the small numbers.

The higher incidence of CS among boys was mainly caused by a higher incidence of emergency CS. Although also among non-breech infants there was a slight but consistent higher incidence of vaginal birth in girls (2% more, data not shown), the difference in gender was much more pronounced in breech positioned infants (5%-6%), especially before publication of the Term Breech Trial. Fetopelvic disproportion may occur more

often in boys because of a higher weight, but possibly male infants may show fetal distress in breech labour more often or more severely than females, contributing to the higher incidence of emergency CS. This explanation is consistent with the finding that adverse perinatal outcome is higher in boys.<sup>13</sup>

Table 3. Literature on incidence of breech position at delivery in boys and girls, including the present data. All concern singleton pregnancies.

					breed	ch position	on		
	Gestation	total			% in	% in			% girls among
Authors	(weeks)	population	n	%	girls	boys	OR	95%-CI	breech
Hall	< 27 – 42+	9117	308	3.4%	3.8%	2.9%	1.31	1.04-1.65	54%
Но	not						•••••		
	mentioned	21243	575	2.7%	3.1%	2.4%	1.30	1.10-1.53	55%
Jonas	20 – 42	56250*	2412	4.3%	4.7%	3.9%	1.21	1.11-1.31	52%
	> 37	53064*	1938	3.7%	4.1%	3.3%	1.26	1.15-1.38	53%
	< 37	3186*	474	14.9%	15.9%	14.1%	1.16	0.95-1.41	46%
Sule	not								
	mentioned	12134	420	3.5%	3.7%	2.2%	1.16	0.96-1.41	51%
Rietberg	24 – 42	1355129	70193	5.2%	5.7%	4.7%	1.22	1.20-1.24	53%
	> 37	1265953	58298	4.6%	5.1%	4.1%	1.26	1.24-1.28	54%

<sup>\*</sup>population number for non-breeches during 3-year study period not mentioned; number derived from 1-year period.

The incidence of babies in breech position at delivery decreased linearly with gestation, apart from the period of 37 and 38 weeks, when the incidence of breech births remained equal. This is likely due to the high incidence of elective caesarean section in breech deliveries at these ages (19% and 39%, respectively, of all breech deliveries at 37 and 38 weeks) (Figure 3). In The Netherlands a policy of spontaneous onset in case of planned vaginal delivery is advised and this is clearly illustrated in Figure 3, in which a peak incidence of 58% vaginal delivery is seen at 40 weeks of gestation. On the contrary the peak incidence of elective CS is seen at 38 weeks.

Some elective caesarean sections will be performed before the planned date because of preterm rupture of membranes or labour, but otherwise such an early planned caesarean delivery does not seem wise, considering the risks of neonatal respiratory morbidity before 39 weeks of gestation.<sup>14-16</sup>

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# 7

# Congenital malformations among infants in breech position: a study of 1.4 million newborns

Christine C.Th. Rietberg
Sabine Anthony
Yvonne Schönbeck
Gerard H.A. Visser

### Submitted

### **ABSTRACT**

**Objective:** To investigate the association between breech presentation and different congenital malformations in relation to fetal gender and gestational age at delivery.

**Study Design:** In a large cohort study of over 1.4 million newborns 70 different congenital malformations were analysed over the nine year period 1996-2004. Multiple pregnancies were excluded. Gestational age was restricted to 24-41 weeks and subdivided into 3 gestational age periods.

**Results:** Of the 1,464,146 newborns, there were 78,133 presenting as a breech. All main subgroups of congenital malformations were more numerous among infants in breech presentation: the overall incidence was 4.4% as compared to 2.4% among vertex presentation. These differences were mainly present in infants born after 32 weeks of gestation. Both in breech and vertex position there was a male excess in all main groups of congenital malformations. Only in neural tube defects and central nervous system malformations a significant female preponderance was present.

**Conclusion:** Breech position is associated with a significantly higher prevalence of congenital malformations.

### INTRODUCTION

Breech presentation is associated with an increased risk of preterm birth,<sup>1-3</sup> low birth weight<sup>4,5</sup> and perinatal morbidity and mortality.<sup>6-8</sup> Some of this can be explained by a more traumatic (vaginal) delivery. However, also congenital abnormalities are overrepresented in breech births. The breech presenting infant probably in itself is associated with more complications and infants with hydrocephalus and congenital malformations of the central nervous system are known to be presenting more often in breech position. Literature studies on the prevalence of congenital malformations in case of breech position are all small and concern between approximately 225 and 2,700 breech presenting newborns, and therefore do not enable to study specific associations between certain congenital malformations and breech presentation.<sup>8-11</sup> We analysed approximately 1.4 million singleton infants of which over 78,000 were in breech position. With these large numbers we were able to come to precise conclusions as to prevalence of different congenital malformations in infants in breech presentation as compared to vertex, distribution among male and female gender and relationship with gestational age. The probable causes for malpresentation will be discussed.

### MATERIALS AND METHODS

In The Netherlands different obstetric caregivers accompany the pregnant woman: low risk pregnancies are supervised by well trained midwives, high risk pregnancies by obstetricians. Both caregivers have separate professional registration systems and register many items about pregnancy, delivery, child and puerperium in the Dutch Obstetric Registry-1 (LVR-1) and 2 (LVR-2), respectively. The registries were introduced in 1985 and 1982, respectively and have extensively been tested, validated and improved. 12 In the Dutch Obstetric Registry-1, participation of midwifery practices during the study years was on average 92%; in the Registry-2, participation of university and teaching hospitals was 100% and of general hospitals 96%. Since 1991 the paediatricians have their own registration in the National Neonatal Registry (LNR). Participation has grown to 100% among NICU's and approximately 50% among general paediatric departments. A method was developed to create a reliable linked perinatal registry, containing detailed perinatal and neonatal information on births in The Netherlands. 13 In this linked registry similar variables of congenital malformations were combined and recoded as some registries provide more detailed coding of congenital malformations than others. The method was validated by comparing the calculated

S4 Chapter 7

Table 1. All analysed congenital malformations, with classification into main groups (expressed in Capitals). n = number, OR = odds ratios, CI = 95% confidence interval; significant findings are presented in bold characters. Some OR's are not shown in the table because of small numbers and lack of significance.

		difference		difference	
		bree	ech-vertex	ma	lle-female
	n	OR	95%-CI	OR	95%-CI
1. Microcephaly	467	2.23	1.67 - 2.97	0.71	0.59 - 0.86
2. Anencephaly	251	1.47	0.92 - 2.34	0.71	0.55 - 0.92
3. Spina bifida + meningo(myelo)cele	758	4.32	3.61 - 5.17	0.92	0.80 - 1.06
4. Encephalocele	72	5.60	3.24 - 9.65	0.55	0.34 - 0.89
NEURAL TUBE DEFECTS	1036	3.62	3.08 - 4.27	0.85	0.75 - 0.96
5. Hydrocephaly / holoprosencephaly	687	6.23	5.25 - 7.39	0.92	0.79 - 1.07
6. Hydrocephaly without NTD	460	5.16	4.15 - 6.43	1.06	0.88 - 1.27
7. Neuromuscular disease	65				
8. Other	947	3.43	2.89 - 4.09	0.95	0.84 - 1.08
9. Malformations CNS not specified	85				
10. Microphtalmia	28				
11. Congenital malformations of the eyes	258	2.79	1.95 - 3.99	0.77	0.60 - 0.99
12. Congenital malformations of the ears	787	2.30	1.85 - 2.87	1.20	1.04 - 1.38
CNS or EYES / EARS	3656	3.17	2.89 - 3.47	0.96	0.90 - 1.02
13. Single umbilical artery	2301	1.48	1.27 - 1.73	0.97	0.90 - 1.06
14. Transposition of great vessels	177	0.52	0.21 - 1.26	2.77	1.98 - 3.89
15. Fallot's Tetralogy	131	1.31	0.67 - 2.58	1.44	1.01 - 2.04
16. Ventricular septum defect	788	2.89	2.36 - 5.53	0.95	0.82 - 1.09
17. Hypoplastic left heart	128	0.72	0.30 - 1.77	1.38	0.97 - 1.97
18. Coarctation aortae	95				
19. Tricuspid atresia / stenosis	17				
20. Complex heart malformation	604	2.26	1.75 - 2.90	1.32	1.12 - 1.55
21. Other	2289	1.61	1.39 - 1.87	1.17	1.08 - 1.27
22. Malformation heart not specified	956	2.16	1.76 - 2.64	1.10	0.97 - 1.25
HEART AND CIRCULATORY SYSTEM	6945	1.76	1.62 - 1.91	1.11	1.06 - 1.17
23. Cleft lip +/- cleft palate	1533	1.22	0.99 - 1.49	1.61	1.45 - 1.78
24. Cleft palate without cleft lip	746	2.46	1.98 - 3.07	0.87	0.75 - 1.01
25. Esophageal atresia / stenosis / fistula	366	2.00	1.42 - 2.81	1.49	1.21 - 1.84
26. Intestinal / anorectal atresia	688	2.06	1.61 - 2.63	1.32	1.14 - 1.54
27. Hirschsprung's disease	74				
28. Malrotation / volvulus	130				
29. Other	1503	2.11	1.79 - 2.48	1.15	1.04 - 1.27
30. Not specified	49				
DIGESTIVE SYSTEM	4697	1.85	1.67 - 2.04	1.28	1.21 - 1.36
31. Choanal atresia	100				
32. Congenital malformations trachea	74				
33. Hypoplasia of the lung	269	6.75	5.17 - 8.82	1.55	1.21 - 1.98

	n	OR	95%-CI	OR	95%-CI
34. Congenital lobular emphysema	8				
35. Hydro / chylo thorax	62				
36. Diaphragmatic hernia	351	1.48	1.00 - 2.19	1.38	1.11 - 1.70
37. Relaxation of the diaphragm	15				
38. Other	759	1.42	1.08 - 1.86	1.12	0.97 - 1.29
39. Not specified	32				
RESPIRATORY SYSTEM	1590	2.37	2.04 - 2.77	1.25	1.13 - 1.38
40. Cryptorchidism	1180	1.19	0.94 - 1.51		
41. Hypospadias and / or epispadias	3053	1.57	1.38 - 1.79	33.50	26.9 - 41.61
42. Bladder extrophia	24				
43. Renal agenesis	267	5.29	3.98 - 7.04	1.65	1.28 - 2.12
44. Congenital cystic kidney	166	3.92	2.64 - 5.82	1.47	1.08 - 2.01
45. Obstructive uropathy	403	1.90	1.37 - 2.65	2.79	2.23 - 3.49
46. Other	4442	1.52	1.36 - 1.70	2.57	2.41 - 2.75
47. Not specified	87				
UROGENITAL SYSTEM	9216	1.62	1.50 - 1.74	4.71	4.46 - 4.98
48. Haemangioma	513	1.22	0.86 - 1.74	0.92	0.78 - 1.10
49. Naevus pigmentosus	540	0.80	0.52 - 1.21	0.89	0.76 - 1.06
50. Other congenital malformations skin	674	1.78	1.37 - 2.31	1.05	0.90 - 1.22
51. Gastroschisis	65				
52. Omphalocele	126				
53. Umbilical hernia	106				
54. Inguinal hernia	331	5.12	3.95 - 6.63	10.24	6.95 - 15.08
55. Other	47				
56. Not specified	1695	0.83	0.66 - 1.04	1.05	0.96 - 1.16
SKIN AND ABDOMINAL WALL	4064	1.45	1.29 - 1.63	1.14	1.07 - 1.21
57. Polydactylism	1431	1.03	0.82 - 1.29	1.31	1.18 - 1.45
58. Syndactylism	926	1.36	1.06 - 1.75	1.78	1.56 - 2.04
59. Reduction defects upper / lower limbs	142	3.47	2.22 - 5.42	1.31	0.94 - 1.84
60. Congenital hip dysplasia	405	10.97	8.97 - 13.41	0.42	0.34 - 0.52
61. Pes equinovarus without NTD	1955	1.36	1.15 - 1.62	1.50	1.37 - 1.64
62. Other	3463	2.54	2.29 - 2.81	1.01	0.95 - 1.08
63. Not specified	159				
SKELETAL AND MUSCULAR SYSTEM	7689	2.11	1.97 - 2.27	1.16	1.11 - 1.22
64. Congenital hypothyreoidism	101	2.86	1.63 - 5.03	1.09	0.73 - 1.61
65. Down syndrome (trisomy 21)	1815	1.93	1.65 - 2.25	1.12	1.02 - 1.23
66. Other chromosomal anomalies	748	3.44	2.83 - 4.18	0.89	0.77 - 1.03
67. Situs inversus	59				
68. Multiple cong. malf. (not listed before)	1252	4.61	4.01 - 5.29	1.09	0.98 - 1.22
69. Other	2451	2.50	2.21 - 2.82	1.06	0.98 - 1.14
70. Not specified	226	2.31	1.54 - 3.48	1.46	1.11 - 1.90
CHROMOSOMAL / SYNDROMAL	6767	2.84	2.65 - 3.05	1.07	1.02 - 1.12

mortality rates of the new perinatal database to mortality rates derived from the civil registries of Statistics Netherlands.<sup>14</sup> Moreover, the completeness of prevalence of congenital malformations in the linked registry was tested by comparing the data with the Eurocat Registration.<sup>15,16</sup> This is a special European registry for congenital malformations, which is very complete, but covers a regional participation. Overall, congenital malformations were equally registered in both the linked and the Eurocat registry. Only a minor underreporting was found in the linked registry for some malformations, such as cleft lip, congenital malformations of the eyes, specific abnormalities of the respiratory system (choanal atresia, lung hypoplasia) and skeletal and muscular system (congenital hip dysplasia, limb reduction defects) and chromosomal abnormalities. This underreporting occurred especially in abnormalities and malformations which do not show easily at birth and are therefore not always registered in the perinatal registry.

For this study, nine years of linked databases were used (1996 - 2004). This resulted in a total of 1,620,246 newborns, which is approximately 91% of all Dutch births in this 9-year period. Multiple pregnancies were excluded and gestational age was restricted to 24 - 41 weeks.

A total of 70 different congenital malformations were analysed, see Table 1. These malformations were subsequently grouped into nine main malformation groups. Analyses were performed on all different congenital malformations, but since results of the separate malformations within each main group were more or less similar, the analysis was later narrowed and restricted to the major groups. The difference in rate of congenital malformations between vertex *vs* breech position was analysed, as well as the difference between gender.

Because congenital malformations and incidence of breech position vary according to gestational age at delivery, sub-analyses were performed on three different gestational age periods: 24-31 weeks, 32-36 weeks and 37-41 weeks.

A chi-square test was used to test the significance of differences.

### **RESULTS**

After exclusion of multiple pregnancies and restriction to the gestational age range of 24 - 41 weeks, there were 1,464,146 infants included in the analysis. Of these 51.4% were male.

One percent of infants was born very preterm (24-31 weeks), 5.6% were born preterm (32-36 weeks) and 93.4% were born at term. Two-and-a-half percent of these infants had

Table 2. Distribution of congenital malformations among males and females in vertex and breech presentation

Position	Gender	total	%	<i>n</i> congenital malformation	%
	Male	714,017	51.5%	20,508	2.9%
	Female	668,120	48.2%	12,972	1.9%
	Unknown	3,886	0.3%	110	
Vertex	Total	1,386,023	100.0%	33,590	2.4%
	Male	36,278	46.4%	1,906	5.3%
	Female	41,478	53.1%	1,518	3.7%
	Unknown	377	0.5%	25	
Breech	Total	78,133	100.0%	3,449	4.4%
	Male	750,295	51.2%	22,414	3.0%
	Female	709,598	48.5%	14,490	2.0%
	Unknown	4,263	0.3%	135	
Total	Total	1,464,156	100.0%	37,039	2.5%

one or more congenital malformations. Among infants in vertex presentation this percentage was 2.4 and among infants born in breech position it was almost twice as high (4.4%; Table 2).

When differentiating between gender, the rate of congenital malformations among male infants in vertex position and breech was 2.9% *vs* 5.3%, while among female infants the rate of congenital malformations was lower, being 1.9% in vertex and 3.7% and breech.

The results in Table 3 show that there was an excess of all different congenital malformations among breech infants, with striking differences in neural tube defects (NTD) and congenital malformations of the central nervous system (CNS), respiratory system, skeletal and muscular system and in infants with multiple / syndromal / chromosomal abnormalities. When dividing the total group into the three predefined gestational age periods there appeared to be hardly any difference in congenital malformations between vertex and breech position in very preterm infants, whereas an excess of all different congenital malformations was found among breeches in the preterm and term groups.

Subsequently gender differences were analysed. Table 4 shows that within all different main groups of congenital malformations there was an excess among male infants as compared to females, except for NTD's, in which a female preponderance was present.

Table 3. Congenital malformations (%) in breech position as compared to vertex with odds ratios (OR) and 95% confidence intervals (CI) for the total gestational age range of 24 – 41 weeks and OR for the three different gestational age periods. Significant findings are presented in bold characters.

DIFFERENCE BREECH – VERTEX									
	2	24 - 41 w	gestat	ion	24-31w	32-36w	37-41w		
	% in breech group	% in vertex group	OR	95%-CI	OR	OR	OR		
congenital malformations TOTAL	4.40	2.42	1.86	1.79-1.92	1.17	1.55	1.46		
neural tube defect	0.22	0.06	3.62	3.08-4.27	0.97	1.90	3.36		
central nervous system & eyes/ears	0.70	0.22	3.17	2.89-3.47	1.03	2.16	2.52		
cardiovasculair system	0.80	0.46	1.76	1.62-1.91	1.11	1.54	1.23		
digestive system	0.56	0.31	1.85	1.67-2.04	1.00	1.30	1.51		
respiratory system	0.24	0.10	2.37	2.04-2.77	1.10	1.69	1.63		
urogenital system	0.98	0.61	1.62	1.50-1.74	1.19	1.52	1.26		
abdominal wall and skin	0.39	0.27	1.45	1.29-1.63	0.90	1.28	0.98		
skeletal and muscular system	1.04	0.50	2.11	1.97-2.27	1.35	2.05	1.75		
chromosomal and syndromal	1.18	0.42	2.84	2.65-3.05	1.30	1.86	2.19		

Table 4. Congenital malformations (%) in male infants as compared to females with odds ratios (OR) and 95% confidence intervals (CI) for the total gestational age range of 24 - 41 weeks and OR for the three different gestational age periods. Significant findings are presented in bold characters.

DIFFERENCE BREECH – VERTEX								
		24 - 41 w	gesta	tion	24-31w	32-36w	37-41w	
	% in male group	% in female group	OR	95%-CI	OR	OR	OR	
congenital malformations TOTAL	2.99	2.04	1.48	1.45-1.51	1.26	1.22	1.50	
neural tube defect	0.06	0.08	0.85	0.75-0.96	0.52	0.55	0.97	
central nervous system & eyes/ears	0.24	0.26	0.96	0.90-1.02	0.67	0.75	1.01	
cardiovasculair system	0.50	0.45	1.11	1.06-1.17	1.07	1.09	1.09	
digestive system	0.36	0.28	1.28	1.21-1.36	1.00	1.11	1.30	
respiratory system	0.12	0.10	1.25	1.13-1.38	1.49	1.12	1.19	
urogenital system	1.02	0.22	4.71	4.46-4.98	2.35	2.77	5.25	
abdominal wall and skin	0.29	0.26	1.14	1.07-1.21	2.69	1.30	1.01	
skeletal and muscular system	0.56	0.48	1.16	1.11-1.22	1.01	1.11	1.16	
chromosomal and syndromal	0.47	0.45	1.07	1.02-1.12	1.06	1.01	1.03	

### DISCUSSION

Several previous studies have shown that infants in breech position have more congenital malformations than infants born in vertex position <sup>8-11,17,18</sup> and it has been postulated that the breech position in itself bears some kind of poor fetal quality, irrespective of the way of delivery.<sup>6,7</sup>

In our study we have classified 70 different congenital malformations into nine main groups (Table 1) and found an excess of all malformations in breech positioned infants (Table 3). These differences were only significant for infants born after 32 weeks of gestation. This is not surprising, since at early gestation 25% - 40% of infants are in breech position<sup>8,19</sup> (see also Chapter 6). This position may, therefore, be considered physiological at early gestation.

The greatest difference in prevalence of congenital malformations between infants born in breech position as compared to those in vertex position concerned NTD's and malformations of the CNS, respiratory system, skeletal - and muscular system and multiple / syndromal / chromosomal anomalies. Regarding NTD's and malformations of the CNS, especially spina bifida with meningomeyelocele (OR 4.32), encephalocele (OR 5.60) and hydrocephalus (OR 6.23) accounted for the large difference. In these malformations mechanical factors may play a major role, but possibly also neurological impairment impedes the fetus from finding it's right position.

The excess of breech position among infants with malformations of the respiratory system (OR 2.37) can largely be explained by the subgroup of infants with lung hypoplasia (OR 6.75). In essence, lunghypoplasia is mostly not an intrinsic congenital malformation, but rather an acquired condition due to severe oligo- or anhydramnios. Strongly diminished amounts of amniotic fluid may cause a mechanical obstruction hampering a spontaneous positional change to a vertex position.

Within the group of urogenital system malformations differences between breech and vertex position were limited, except for renal agenesis and congenital cystic kidney disease. Again severe oligo- or anhydramnios is likely to play a crucial role.

Impaired fetal movements with decreased or sometimes increased fetal tonus may explain the higher incidence of breech position in case of multiple / syndromal / chromosomal anomalies. This may also hold for infants with congenital malformations of the skeletal and muscular system in whom reduction defects of upper or lower limbs and other malformations of the skeletal and muscular system had a high incidence of breech position.

The strong association between congenital hip dysplasia and breech position (OR > 10 in our study) is well known.<sup>20-23</sup> Still this malformation did not cause the high incidence of

breech position in the overall group of skeletal and muscular malformations, since only 405 cases of congenital hip dysplasia were registered. Probably there is underreporting of hip dysplasia in our registry, since this malformation may only be detected somewhat later in life, or remains out of the registration of the paediatrician, because the registry only deals with admitted infants and not with outpatient infants. The strong association of hip dysplasia with female gender (OR 0.42), known from literature, <sup>22-25</sup> was also found in our study.

Other factors than the slightly higher prevalence of females among breech positioned newborns<sup>8,19</sup> (see also Chapter 6) must account for the excess of hip dysplasia in female babies. Some have suggested a hormonal relationship with neonatal hip instability as an explanation for this female excess, but this could not be confirmed.<sup>26</sup>

The overall male-to-female ratio of our study was 1.06, or differently 51.5% of infants were of male gender. This is in correspondence with literature.<sup>27,28</sup> Among breech infants there was a female preponderance, with an opposite female-to-male ratio of 1.14, or differently 46.7% males. This is consistent with earlier findings, where from 32 weeks onwards girls were more often found to be born in breech position (see chapter 6). Overall, male infants had a 1.5 times higher risk of having congenital malformations than female infants and this held for both vertex and breech position. There was especially a high male preponderance for obstructive uropathy and other malformations of the urogenital system, which is in agreement with literature.<sup>29</sup> The high male preponderance for transposition of the great heart vessels (OR 2.77) and Fallot's tetralogy, has also been found before.<sup>30</sup>

Only for NTD's there was a significant excess of female infants, especially in the (very) preterm group. In literature there is controversy about gender differences among NTD's and CNS malformations. Pinar *et al.*<sup>31</sup> and Shaw *et al.*<sup>32</sup> found a 1:1 ratio within all subgroups. Dolk *et al.*,<sup>33</sup> however, found a female excess for encephalocele in the United Kingdom, but a male excess in Continental Europe, while a female excess was found for anencephaly with accompanying spina bifida, inencephaly and upper spina bifida in both geographic areas. Other findings<sup>34-36</sup> suggest that gender differences are associated with the level of the defect. In these studies females seemed prone to defects of neurulation, leading to cranial lesions and superior spina bifida with or without occipital lesions, while males seemed prone to defects of canalisation, leading to mostly isolated lower spinal lesions. Those findings are most consistent with ours.

### **CONCLUSIONS**

Breech position is associated with a significantly higher prevalence of congenital malformations than vertex positioned infants. Especially neural tube defects and congenital malformations of the central nervous system, respiratory system, skeletal and muscular system and multiple / syndromal / chromosomal abnormalities are over-represented among breech infants. Male excess was found in all main groups of congenital malformations, except for neural tube defects / central nervous system malformations, in which a significant female preponderance was present. It is likely that congenital malformations result in breech position, rather than the reverse.

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## 8

Summary and general discussion

### **SUMMARY**

This thesis deals with the term fetus in breech position, with questions regarding the safety of the different modes of delivery and with variables determining this safety. In The Netherlands the overall caesarean section (CS) rate for term breech delivery had gradually risen to 50% by the year 2000. In that year publication of the results of the Term Breech Trial (TBT) led to a dramatically fast increase of the CS rate to 80% in two months time, a phenomenon not often seen before. It also led to discussions about the validity of the trial and its applicability to the Dutch situation.

In **Chapter 1** a brief review of the literature is given and the aim of this thesis is presented. This thesis aims to answer the following questions:

- 1. What was the perinatal mortality and morbidity rate in The Netherlands in case of a term breech presentation before publication of the Term Breech Trial in relation to the different modes of delivery?
- 2. What was the effect of the TBT on medical intervention behaviour and perinatal outcome in The Netherlands?
- 3. Which factors have contributed to the change in policy following the publication of the TBT.
- 4. What is with a policy that has changed as a result of the TBT the current risk of perinatal mortality and morbidity with a vaginal trial of labour and a planned elective caesarean section?
- 5. What is the male to female ratio for infants presenting in breech in relation to gestational age?
- 6. What is the correlation between breech presentation and different congenital malformations in relation to fetal gender and gestational age at delivery.

In **Chapter 2** perinatal mortality and direct morbidity is studied in term infants born in breech position in relation to the mode of delivery. Until publication of the TBT, The Netherlands had a relatively conservative approach concerning breech delivery, resulting in a 75% trial of labour and an overall vaginal delivery rate of 50%. To study perinatal mortality and morbidity in relation to the different modes of delivery before publication of the TBT, we used data from the National Obstetric Database (LVR-2). All singleton breech infants with a gestational age of 37 - 41 weeks and born between 1995 - 1999 were analysed. Lethal congenital malformations and antenatal fetal deaths were excluded. Birth weight was restricted to  $\leq 4000g$  and a second analysis was performed on birth weights > 4000g. A total of 31,439 neonates with a birth weight  $\leq 4000g$  and 2385

Summary 97

neonates weighing > 4000g were studied. Four different modes of delivery were analysed: planned CS for reason of breech only, planned CS for other reasons, emergency CS and vaginal delivery. The latter two groups were later combined into a vaginal trial of labour (VTOL) group. Perinatal mortality was defined as intrapartum death or death within a week following birth. Perinatal morbidity was defined as a low 5-minute Apgar score (i.e. < 7) or birth trauma, which was classified as intracerebral haemorrhage, cephalic haematoma, facial nerve palsy, brachial plexus lesion, fracture of clavicle, humerus or femur and other trauma.

To study possible interactions of different parameters on neonatal outcome, such as birth weight, gestational age and parity, we used logistic regression analysis. Only birth weight appeared to be a significant factor and odds ratios were corrected for this. Mortality in the planned CS (for breech) group was twice as low as in the vaginal trial of labour group  $(0.17\%\ vs\ 0.39\%;\ OR\ 0.59;\ 95\%-CI\ 0.26-1.21)$ . Low 5-minute Apgar score was seven times as low  $(0.4\%\ vs\ 2.8\%;\ OR\ 0.17;\ 95\%-CI\ 0.11-0.27$ ), and birth trauma was three times as low  $(0.17\%\ vs\ 0.50\%;\ OR\ 0.33;\ 95\%-CI\ 0.16-0.71)$ . In infants > 4000g birth trauma was restricted to vaginal delivery (1.3%). Overall, results in these infants were similar to those weighing  $\leq 4000\ g$ .

In order to investigate if induction or augmentation of labour was related to outcome a sub-analysis was performed on 16,884 deliveries before 41 completed weeks, in which no oxytocic drugs were used. Also in this subgroup mortality, low Apgar score and birth trauma were significantly lower in the planned CS (breech) group than in the vaginal trial of labour group.

To investigate whether different local policies affected outcome, all 119 hospitals were subdivided according to their overall planned CS rate for breech presentation (0 - 17%; 17% - 26%; > 26%). Similar results were found in all three groups.

Complications with the after-coming head increased with increasing duration of the second stage of vaginal labour (13% with a second stage of  $\leq$  30 minutes; 16% with a second stage lasting 30-60 minutes; 20% with a second stage of 60-90 minutes). Assisted vaginal delivery with forceps was clearly associated with higher mortality (1.0% vs 0.3%), lower Apgar score (9.2% vs 2.1%) and increased incidence of birth trauma (1.9% vs 0.4%).

Caesarean section leads to an increased risk of maternal morbidity and mortality, probably resulting in an increased perinatal risk in future pregnancies. Therefore, positive effects for the child need to be carefully weighed against increased maternal (long term) risks with an increase in caesarean sections.

In Chapter 3 the tremendous change in medical intervention behaviour that occurred after publication of the TBT in October 2000 is described and the effect this has had on overall mortality and morbidity among term infants born in breech position is analysed. Total CS rate for term breeches increased from 50% to 80% in the two months after publication of the TBT, mainly as a result of a large increase in planned elective CS (because of breech position only). This increase occurred in virtually all Dutch hospitals. The intervention rates remained stable after the initial rise. To study the effect of this change in policy, the 33-months period before publication of the TBT was compared to the 25-months period thereafter. Data was derived from the Dutch Obstetric Registry (part of The Netherlands Perinatal Registry) which covers almost 100% of secondary care deliveries. Analysis on 35,453 term singleton breech infants was performed, using the same methodology as described in chapter 2. Perinatal mortality among breech infants weighing ≤ 4000g decreased from 0.35% to 0.18% (OR 0.53; 95%-Cl 0.33-0.83), and low 5-minute Appar score and birth trauma decreased from 2.4% to 1.1% (OR 0.43; 95%-CI 0.36-0.52) and from 0.29% to 0.08% (OR 0.26; 95%-CI 0.14-0.50), respectively. A similar trend occurred in infants > 4000g. This decrease in unfavourable perinatal outcome can mainly be attributed to the increase in planned elective CS (because of breech only). After publication of the TBT neonatal outcome after emergency CS seemed to be better, but this was only significant for Apgar score. A lower incidence of birth trauma in the vaginal delivery group did not reach statistical significance.

The slightly better outcome after emergency CS and vaginal delivery may indicate that the decision to stop VTOL and convert to emergency CS is taken earlier in the process of labour and that for the remaining 20% of vaginal deliveries a better risk selection had taken place. The change in CS policy has resulted in about 2000 extra CS per year for term breech delivery and with this policy 11 more infants survive, i.e. 175 extra CS for every infant saved. This has to be weighed against adverse maternal and fetal risks (uterine rupture, placental scar invasion) in subsequent pregnancies.

In **Chapter 4** linked obstetric and neonatal databases were used to study mortality and severe neonatal morbidity in more detail in 11,580 term singleton breeches, born in the 3-year period 2001 – 2003. Participation in the Obstetric Registry is approximately 100%, while approximately 70% of Dutch hospitals participate in the Neonatal Registry. Thus a total of 14,048 singleton infants in breech could be analysed, which is about two-thirds of all infants born in breech position during the study period. Of these, 11,580 infants were born at term (37-41 weeks). Severe perinatal morbidity was defined as seizures, hypoxicischemic encephalopathy (HIE) (according to Sarnat classification grades 1, 2 or 3),

traumatic haemorrhage (intracranial haemorrhage, such as cephalic, subdural, subarachnoidal haematoma and tentorial rupture), fractures and paralyses. Other morbidity included low 5-minute Apgar scores (AS) of < 4 and < 7, hyperbilirubinaemia and pulmonary morbidity (Idiopatic Respiratory Distress Syndrome, pneumothorax, wet lung). A logistic regression model was used in which mode of delivery, parity (multi-parity to primi-parity [first born infant]), gestational age (per week), gender and birth weight were included.

Intrapartum and neonatal mortality was 0.38% in the VTOL group as compared to 0% in the elective CS group. Severe morbidity was present in 1.35% of infants born vaginally and in 0.48% of infants delivered by emergency CS (total VTOL 0.92%), in contrast to 0.16% in the elective CS group. Mortality and severe morbidity together occurred in 1.29% after VTOL and in 0.16% after elective CS, i.e. a difference of more than one percent. Outcome of infants after a CS for other reasons showed a combined mortality / morbidity of 0.56%. Detailed analysis showed that mortality had mainly been due to asphyxia (15/17 cases, al born after VTOL). One infant died of mild asphyxia plus sepsis (after VTOL) and one of unknown reasons (after planned CS for other reasons). The excess morbidity in the VTOL group was due to fetal asphyxia, frequently combined with a difficult and traumatic vaginal delivery. Wet lung occurred significantly more often after elective CS (1.45% as compared to 0.87% in VTOL; OR 1.67; 95%-CI 1.13-2.48). This difference can be attributed to a higher incidence of wet lung after CS at 37 and 38 weeks of gestation.

Five minute Apgar scores < 4 occurred more frequently after VTOL than after elective CS  $(0.31\% \ vs\ 0.02\%;\ OR\ 17.0;\ 95\%-Cl\ 2.22-129.59)$  as did a low 5-minute AS < 7  $(1.58\% \ vs\ 0.13\%;\ OR\ 12.62;\ 95\%-Cl\ 5.79-27.53)$ . Hyperbilirubinaemia occurred more often in the VTOL group, as did the need for resuscitation at birth.

Small-for-date infants (< 2500g at term) had a higher morbidity / mortality after vaginal delivery than infants with normal birth weights. This was confirmed by logistic regression analysis, in which a significant difference was found for the mode of delivery (planned elective CS *vs* VTOL: OR 0.13; 95%-CI 0.06-0.26) and for small-for-dates (birth weight < 2500g *vs* 2500-4000g: OR 3.09; 95%-CI 1.45-6.59). No difference was found for gender, parity or gestational age.

In conclusion, planned vaginal delivery bears 1% greater risk of mortality / severe morbidity than planned elective CS. Planned CS should preferably not be performed before 39 completed weeks because of an increased risk of wet lung.

In **Chapter 5** the results of a survey questionnaire are presented. This survey was held among all Dutch obstetric departments to investigate the factors that caused the rapid and dramatic increase in CS rate among term breech births. The response was 86%. On the basis of a model, four different influences were investigated: the influence of the TBT itself, the patient, the Dutch Society of Obstetrics & Gynaecology and the professional autonomy of the doctor. A significant correlation was found between patient influence and the increase in CS rate after publication of the TBT. Also the influence of the TBT itself on policy and the degree to which patients follow the doctor's advice appeared significant factors. No significant correlations with CS% could be found for the other influences. From the regression model and the answers given by the departments we could conclude that patient influence, directed by strong media attention and amplified by the Dutch Society's stimulation to communicate trial-results with the patient, seemed to be the most important factor for the change in medical practice in case of term breech.

In **Chapter 6** gender differences among infants in breech position were studied. The overall male to female ratio at birth irrespective of fetal position is in favour of male infants (51.5% male). By using data derived from the National Obstetric Database (LVR-2), 1.3 million singleton infants born between 1995 – 2002 were studied. Of these, 70,125 were in breech position at delivery (24 - 42 weeks). From 32 weeks onwards significantly more girls than boys were born in breech position, with only 43.4% boys at 40 weeks gestation. Breech position at delivery is known to depend on gestational age and birth weight. We find that fetal gender seems to be an independent factor as well. The aetiology is unknown, but may be related to differences in size and shape of the fetal pelvis or hips.

In **Chapter 7** congenital malformations among infants in breech are discussed. The increased perinatal risks of mortality and morbidity associated with breech position are related to a higher frequency of low birth weight, preterm birth and traumatic delivery. But also congenital malformations occur more frequently and contribute significantly to the mortality risks of breech. Literature on the prevalence of congenital malformations in case of breech is restricted to small studies (up to 2700 cases) and can therefore not be used to study correlations of specific malformations with breech position. In this chapter we analysed 1,620,246 singleton infants of which 78,133 were in breech, by using a linked perinatal registry of the Dutch Obstetric Registries of midwives (LVR-1) and obstetricians (LVR-2), covering the period 1996-2004. Seventy different congenital malformations were analysed and divided into nine main malformation subgroups. Differences in rate between

vertex and breech as well as between male and female gender were analysed for deliveries for the period 24 - 41 weeks gestation.

Among infants in vertex position, 2.4% had congenital malformations and among breech infants this was 4.4% (in males 2.9% and 5.3% and in females 1.9% and 3.7%, respectively). An excess of congenital malformations in breech infants was found for all major malformations and especially for neural tube defects (NTD) and congenital malformations of the central nervous system (CNS), respiratory system, skeletal and muscular system and in infants with multiple / syndromal / chromosomal abnormalities. This excess was present in preterm and term infants (32-36 and 37-41 weeks), but not in infants born very preterm (24-31 weeks). This is likely to be related to the fact that at early gestation 25%-40% of all infants are in breech position, so this position can be considered as physiologic at early age. A male excess was present for all different groups of malformations, except for NTD, in which a clear female preponderance was observed.

The excess in infants with NTD and malformations of the CNS can be explained by a mechanical factor (hydrocephalus, encephalocele) but also by neurological impairment, impeding the fetus to find it's right position. The excess in infants with respiratory system malformations is explained by the subgroup with lung hypoplasia, which is mostly caused by strongly diminished amniotic fluid, causing mechanical obstruction to change to vertex. This is also the case for renal agenesis and congenital cystic kidney disease. Impaired fetal movements with sometimes decreased or increased fetal tonus may explain the high rate among infants with multiple / syndromal / chromosomal abnormalities and abnormalities of the skeletal and muscular system. There was a strong correlation between congenital hip dysplasia and breech position (OR > 10). This is well known from literature, just as the strong correlation of congenital hip dysplasia with female gender, which was also present in our series (OR 0.42). The aetiology of the latter is unknown.

Overall, breech position was associated with a significantly increased prevalence of congenital malformations. Male infants had a 1.5 times higher risk of having a congenital malformation than females, both for breech and for vertex position, except for NTD's and other CNS malformations, in which there was a female preponderance. It is likely that congenital malformations result in breech position, rather than the reverse.

#### CONCLUSIONS

The key findings of this thesis are:

 The risks of direct perinatal mortality and morbidity, defined as low 5-minute Apgar score and trauma, are higher with vaginal trial of labour than with planned elective CS.

- No subgroup could be defined in which vaginal delivery of a breech infant appears to be as save as planned CS.
- The tremendous change in policy, with a shift from 50% to 80% CS in term breech deliveries, has resulted in a decrease of intrapartum and neonatal mortality from 0.35% to 0.18%.
- When studying perinatal outcome in more detail by using linked obstetric and neonatal databases, the above conclusion is further supported: delivery after VTOL has a surplus risk of perinatal mortality / severe morbidity of more than 1%.
- Elective CS for breech should not be performed before 39 weeks of gestation, given the risks of wet lung at earlier age, even though this implies that more CS's will have to be performed at night, due to spontaneous onset of labour before the planned date.
- From 32 weeks of gestation onwards there is a significant preponderance of female infants in breech position and girls are delivered more often vaginally.
- Breech position is associated with a significantly higher prevalence of congenital malformations than vertex position.
- Male infants have a 1.5 times higher risk of having a congenital malformation than females, both in breech and in vertex position, except for neural tube defects and malformations of the central nervous system.
- The shift from 50% to 80% CS among term breech deliveries following publication
  of the TBT occurred in almost all obstetric departments in The Netherlands.
  Although 94% of departments report that the influence of the TBT had been large,
  64% do not think the study was scientifically well performed or do not find the
  study applicable to the Dutch situation.
- Pressure from the patient, influenced by strong media attention and amplified by the Dutch Society's stimulation to communicate trial-results with the patient, seems to be the most important factor that has contributed to the change in clinical practice.

#### **GENERAL DISCUSSION**

The results published in this thesis are based on an unprecedented case base, giving strong statistical support to its conclusions and confirming earlier studies. Quite apart from the clinical conclusions we can therefore also state that the Dutch Perinatal Database offers a significant opportunity to validate or reject hypotheses about the clinical sense of obstetric policies.

## Implications of the mode of delivery for fetus and mother

#### Perinatal outcome

In the years before the publication of the Term Breech Trial in 2000, 75% of Dutch women with a term fetus in breech position had a vaginal trial of labour (VTOL), of which two-third was successful. This resulted in an overall CS rate of 50%. Our analysis of this policy revealed that mortality among infants delivered by planned elective CS was lower (0.17%) as compared to infants delivered by planned vaginal delivery (0.39%). Significant differences were also observed for low 5-minute Apgar score and birth trauma.

The TBT resulted in a dramatic rise in CS rate to 80% in the two months after publication, all attributable to an increase in planned elective CS rate. With this changed policy overall perinatal mortality among term breech infants dropped from 0.35% to 0.18%. To calculate how many CS's need to be done in order 'to save' one child, one needs to consider the diminishing gain: the higher the pre-existing intervention rate is, the more CS's need to be performed to lower mortality. If, with a CS rate of 50%, all infants born after VTOL would be delivered by planned CS instead, approximately 320 extra planned CS's would be needed to 'save' one extra child (Chapter 2).

In reality this turns out differently: with the increase in CS rate from 50% to 80%, 2000 extra CS's performed per year will save the life of 11 infants (Chapter 3). So, for every infant 'saved' with this new policy, about 175 extra caesarean sections will have been performed. These findings are consistent with those of Bingham and Lilford<sup>1</sup>, who applied their decision theory on the management of the selected term breech 18 years ago. They estimated that the increased risk of perinatal death and of serious cerebral dysfunction due to VTOL would be two to four per 1000 infants. The same probability was found for neurological handicaps, at least until discharge from the hospital.

Our findings are also in agreement with the results of the TBT, although the effect of planned CS is less profitable than the effect found in the TBT. The reasons for this can be various: due to the Dutch selection system only high risk pregnancies are supervised by obstetricians, leading to an overall high percentage of breech deliveries under the care of the obstetrician (8.2%). Together with the former high rate of vaginal delivery this leads to

a high level of expertise. Furthermore, the results of this randomised trial might not be representative for reasons described by Glezerman<sup>2</sup> (violation of inclusion criteria, incompatible inter-institutional variations of level of care, no attendance of clinicians with adequate expertise, perinatal mortality and morbidity not related to the mode of delivery) and by Kotaska<sup>3</sup> (bias of licence, homogenisation of the study population and clinical intervention by large scale randomisation, resulting in an average level of care in an average population).

From our studies we conclude that a planned CS is to the advantage of the infant. But there is a reverse to every medal and this reverse might be paid by the mother or her future offspring.

### Long term consequences for the infant

Long term consequences of vaginal or abdominal breech delivery are hard to assess. There have been some long term studies. In The Netherlands two studies on long term infant morbidity in case of breech delivery were performed in the past decades.

In 1981 Faber-Nijholt *et al.*<sup>4</sup> performed a long term case-control study in The Netherlands, studying a group of 348 infants, born as a singleton in breech or as a twin in breech (case), with the other twin in vertex position (control) after 28 weeks of gestation and weighing > 1000g. The control-group for the singletons was composed of infants born in the same period in vertex position. In the study period breech delivery was associated with a very low CS rate of 20%. Neurological examination at the age of 3-10 years did not show an increased frequency of serious dysfunction (i.e. obvious handicaps) among breech born infants. Minor to minimal dysfunctions, however, were found more often among breech infants. After correcting for other influences these proved to be statistically not significant. Also behavioural and learning difficulties were not found. Faber concluded that the main danger of breech presentation is in the associated complications of pregnancy and that there is no reason to advocate a higher frequency of abdominal delivery than the 20% they observed.

In 1989 de Leeuw *et al.*<sup>5</sup> performed a study in The Netherlands in 268 singleton infants in breech, weighing > 500g. The CS rate was 34%. No difference in neonatal outcome was found between vaginal delivery and CS. In a follow-up study 96% of the infants were examined at the age of one. Again no differences were found with respect to the mode of delivery. It was concluded that most of the patients with a singleton infant in breech presentation can deliver vaginally without increased neonatal mortality or morbidity and that several classic obstetric factors (parity, type of breech, birth weight) have a lower

discriminating value for the mode of delivery than was assumed. Progress of labour was an important factor in determining the mode of delivery.

Danielian *et al.*<sup>6</sup> presented a follow-up at school age of 1,645 breech infants and found no significant differences in severe handicap or other outcome measurements between the 64% born after vaginal trial of labour (VTOL) and the 36% born after planned caesarean section (pCS). Even though this study investigates quite a number of infants (269 infants with major and minor handicaps (including speech / growth / general delay, gross motor, convulsions, visual, auditory, psychiatric handicaps) among the 1387 infants included in the follow-up (16% lost to follow-up), of which 27 had severe handicaps), the numbers are still small to discriminate.

Krebs *et al.*<sup>7</sup> carried out a case-control follow-up study in Denmark by a questionnaire to the parents to investigate if a low Apgar score in breech presentation at term was associated with an increased risk of neurological handicap or minor disability. One hundred and five infants with 5-minute Apgar scores < 7 and 218 controls (AS  $\geq$  7) were evaluated between ages 6 and 14. Response to the questionnaire was 83% and 87% respectively. Four cases (4.6%) and one control (0.5%) had cerebral palsy. Speech/language problems were reported more frequently in the cases than in the controls (10.6% vs 3.2%; OR 0.3; CI 0.1-0.8) and absence of handicap or disability was reported in 75% of cases as compared to 92% of controls.

In the studies of Münstedt *et al.*<sup>8</sup> and of Rosen *et al.*<sup>9</sup> a correlation between late infant morbidity and mode of delivery in term breech infants could not be confirmed. Both studies involve only small numbers.

Also a 2-year follow-up of the Term Breech Trial did not confirm this association. However, due to lack of follow-up (920 infants of the original 2078 infants) this study was underpowered.<sup>10</sup>

Recently two reports were published on follow-up of breech delivered infants. The first was again by Krebs and Langhoff-Roos<sup>11</sup> from Denmark and reports on the relation between breech presentation at term and epilepsy in childhood. Breech presentation was found to be a risk factor for epilepsy (OR 1.2; 95%-CI 1.1-1.3), irrespective of the mode of delivery; however breech infants with epilepsy were more often small for gestational age (9.7%) than breech infants without epilepsy (4.7%) and they conclude that the increased risk of epilepsy in term breech infants is not related to intrapartum events, but to growth restriction in pregnancy. This finding is in line with their previous findings that also the risk of cerebral palsy among term breech presentation infants does not seem to be related to mode of delivery, but is more likely linked to a higher rate of small-for-dates in breech infants.<sup>12</sup>

Molkenboer *et al.*<sup>13</sup> recently investigated neuro-developmental outcome of 183 out of 203 term breech infants at two years of age in relation to the mode of delivery, using a questionnaire to the parents. They found evidence of interaction between planned vaginal delivery and birth weight, with a significantly higher risk of neuro-developmental delay in infants with a birth weight greater than 3500g.

In our study using linked databases, we found 57 infants with serious morbidity. These concerned 39 out of 4257 (0.92%) infants born after planned vaginal delivery, 9 out of 5524 (0.16%) infants born after planned CS for breech presentation (OR planned elective CS vs VTOL 0.13; 95%-CI 0.06-0.26) and 9 out of 1799 (0.50%) infants born after CS for other reasons. After VTOL, 7 infants had serious hypoxic encephalopathy (Sarnat grade 2 and 3) and 15 had brachial plexus palsy (of which 2 also had a Sarnat 2). Both conditions are known to cause serious impairment in later life. After planned CS no encephalopathy was seen and 2 infants had an brachial plexus palsy. Even though a proportion of infants with brachial plexus palsy will show full spontaneous recovery, for the remainder of infants and their families it will have deleterious medical, psychological, and socio-economic sequelae. 14-16 Four out of 13 infants with very low 5-minute Apgar scores (AS < 4) in the VTOL group had Sarnat grade 2 or 3, while the one infant with low AS in the planned CS group had no neurological impairment. Sub-analysis showed that the excess morbidity in the VTOL group was due to fetal asphyxia, frequently combined with a traumatic delivery. This data shows that large samples are necessary to assess the real effects of treatment modalities. Although there is no certainty as to how these infants will do at an older age, the data strongly suggests that the mode of delivery does make a difference.

#### Maternal complications

Maternal complications related to a caesarean section are a concern. With respect to these a distinction should be made between direct risks in relation to the mode of delivery and subsequent indirect risks due to the uterine scar after a CS.

#### Direct risk of maternal mortality and morbidity

Maternal mortality is higher after CS than after vaginal delivery. Percentages in literature are often based on planned and emergency CS's in situations with pre-existing pathology. However, the maternal mortality risk of planned CS is significantly lower than the risks associated with emergency and intrapartum CS. 20,21

The increase of CS after the TBT has led to a shift from emergency CS to planned elective CS. According to the calculations by Vandenbussche and Oepkes<sup>22</sup> using our recorded numbers of breech deliveries (Chapter 3)<sup>23</sup>, and maternal mortality figures taken from the two most recent Confidential Enquiries into Maternal Deaths (CEMD) in the United Kingdom<sup>24,25</sup> covering the same period, the observed change in practice could lead to either the saving of one maternal life every 14 years or the loss of one maternal life every 6 years. Based on this calculation it is expected that the new policy will have little or no effect on direct maternal mortality. It is therefore not likely that an increase in planned CS, accompanied by a decrease in emergency CS, will lead to an increase in direct maternal mortality.

However, five cases of maternal mortality have occurred in The Netherlands since 2000 in relation to planned CS because of breech position and this is often mentioned in discussions. But only two of these five had an elective planned CS with no additional pathology. The other three underwent a non-elective planned CS: the first case had had a previous CS, the second case had a history of a difficult vaginal delivery with forceps after failed vacuum extraction. Both women had a BMI > 40, a condition known to have a significantly increased risk of failed trial of labour (> 30% failure; OR 2.2; 95%-CI 1.1-4.4). The third case had multiple gestation.

Also maternal morbidity is reported to be lower after planned CS compared with emergency CS.<sup>27</sup> The direct risk of infectious morbidity is increased after CS. The risk of infectious morbidity remains controversial in case of a previous CS. Hibbard *et al.*<sup>33</sup> and Taylor *et al.*<sup>35</sup> found this risk to be increased after VTOL; Mozurkewich *et al.*<sup>36</sup> found a decreased risk after VTOL as compared to planned repeat CS.

### Long term maternal consequences

There should be concern as to long-term consequences for the mother: subsequent pregnancy after a previous CS bears the risk of uterine rupture, placenta praevia and increta, with possibly severe consequences like serious haemorrhage and peripartum hysterectomy. Although some studies do not find clear associations with late maternal complications, others describe a significantly increased maternal risk for major complications in case of VTOL after previous CS, especially uterine rupture, with a subsequent higher rate of premature delivery, neonatal intensive care, perinatal mortality and low AS. Especially labour induction with prostaglandins is widely associated with uterine rupture as compared to spontaneous labour or repeat CS. 32,35,37,38

These findings are consistent with the findings of Kwee et al.<sup>39</sup> who performed a prospective study in 38% of hospitals in The Netherlands. She found 1.1% uterine

ruptures among women with a previous CS, accompanied by four perinatal deaths (1.2/1000 VTOL). Of these women with previous CS, 72% had a VTOL, with an overall vaginal birth after CS rate (VBAC) of 54%. A significant increase of uterine rupture after previous CS was found with the use of prostaglandin E2 for labour induction (OR 6.8; 95%-CI 3.2-14.3). Uterine rupture resulted in hysterectomy in 0.9/1000 VTOL.

The need of emergency peripartum hysterectomy (EPH) is associated with CS. Kwee *et al.*<sup>40</sup> found this risk to be 0.12% for a vaginal delivery and 0.47% for CS (RR 4.9; 95%-CI 1.6-15.3). In case of vaginal delivery after previous CS this risk increased further to 0.80% (RR 8.3; 95%-CI 2.2-31.8) and for repeat CS it was 6.2% (RR 64.7; 95%-CI 38.9-107.7). In the latter group there were 13 EPH, twice for uterine rupture and 11 times for placenta accreta (8 placenta praevia, 1 low-lying and 2 normally localised placentas).

Returning to the calculations earlier in this chapter we will attempt to make up the balance for The Netherlands. With the increase of CS from 50% to 80% in term breeches approximately 11 infants are 'saved' per year at an expense of 2000 extra CS. Since the probability of a subsequent pregnancy is 52% for Dutch women<sup>41</sup>, the increase of 2000 extra CS's implies an increase of 1000 women with subsequent pregnancies with a uterine scar. Of these, 72% will undergo a VTOL and there are likely to be 10 uterine ruptures (1.5% during VTOL) and 1 perinatal death (1.2/1000 VTOL). So the net benefits for the infants is not 11 but 10 infants per year 'saved' by the increase in CS rate.

The increase of 1000 women becoming pregnant with a uterine scar, will result in about 10 uterine ruptures and 3 emergency hysterectomies (for uterine rupture, placenta accreta, placenta praevia). A recent study in The Netherlands showed that 2 out of 48 (4%) women, in whom an emergency peripartum hysterectomy had to be performed, died. Although this data is insufficient to calculate actual maternal risks with some precision, one may assume that for every 80 infants 'saved' by CS for breech (in about 8 years) one woman will die.

#### **External cephalic version**

Because vaginal breech delivery is generally thought to increase the risk of perinatal mortality and morbidity, <sup>42</sup> a choice to perform a CS is widely accepted these last decades. This has led to a tremendous rise in caesarean section rate. In some institutions this rate approaches 100%. The performance of a CS not only directly increases the CS rate, but also has an impact on future pregnancies, thus further increasing the overall CS rate. In order to reduce this high CS rate, with its associated maternal morbidity risk, external cephalic version (ECV) has been advocated as an

alternative choice. The present guideline of the Dutch Society of Obstetrics and Gynaecology explicitly states that the possibility of external cephalic version should be discussed with the patient.

Randomised controlled trials have shown that ECV does not seem useful before 34 weeks of gestation, since this does not result in a decrease of term breeches. ECV should, therefore, be preformed later during the third trimester, when the chances for a spontaneous conversion into a cephalic position are lower.

RCT's have shown that the incidence of term breech position can be reduced, by performing an ECV at around 36-37 weeks of gestation.<sup>46-50</sup> ECV late in gestation has the additional advantage that in case of fetal distress immediate delivery can be performed without serious concern for fetal maturation.

The success rate of ECV varies according to literature from 39% to as high as 86%. 46-59 Without a trial of ECV or after unsuccessful ECV a proportion of infants will show spontaneous cephalic version. The rates reported in literature vary, though cephalic version after unsuccessful ECV seems more unusual than spontaneous cephalic version without a trial of ECV.

Factors, considered as contra-indications to ECV are the following: instable fetal position, non-reassuring fetal heart pattern, antepartum haemorrhage, patient's refusal, <sup>52</sup> complete / multiple loops of nuchal umbilical cord, extension of the fetal head, oligohydramnios, rupture of membranes, history of placental abruption, poorly controlled hypertension, <sup>60</sup> fetal growth retardation, multiple pregnancy, history of uterine operation and placenta praevia or anterior position. <sup>61</sup> A previous caesarean section is considered as a relative contra-indication, and successful ECV's without complications in case of previous CS have been described. <sup>62-64</sup>

With respect to fetal and maternal risk, external cephalic version may be considered as a safe procedure with minimal risks, when careful attention is given to contra-indications. Since the introduction of ultrasonic examination, fetal deaths in relation to ECV have been extremely rare. Fetal bradycardia or decelerations are reported, but are usually transient and without any consequences. Nassar *et al.* Performed a systematic review of the literature. He found no increased risk of antepartum fetal death associated with ECV among eleven studies with a total of 2503 women. Also no uterine rupture, placental abruption, pre-labour rupture of membranes or cord prolaps after ECV were reported. Onset of labour within 24 hours and nuchal cord were non-significantly higher among women who had an ECV, compared with those with a persistent breech without a trial of ECV.

In a minority of ECV's complications do occur. Most reported are persistent fetal bradycardia, requiring emergency CS. Also vaginal bleeding has been reported. These complications, though rare, do support the recommendation that ECV is performed in a facility which is able to provide an emergency CS under close fetal monitoring during and after the procedure. Because of the possibility of fetomaternal transfusion, anti-Rhesus-D immunoglobulines need to be administered to Rhesus-D negative women.

The use of tocolysis to facilitate ECV and improve success rates remains controversial but appears to help in nulliparous women.<sup>56,69</sup> Other measures to improve success rates, such as spinal or epidural analgesia, amnioinfusion or fetal acoustic stimulation have not proved to be effective.<sup>69</sup>

From literature (USA, Hong Kong, Ireland) it appears that – even if success rates of ECV are high (with a reduction of CS after ECV from 83% to 37% in the US)<sup>65</sup> – ECV will not have a major impact on overall CS rate. According to one study it will not reduce the overall CS rate by more than 1%. In part this seems to be due to the fact that the CS rate in women after successful ECV is higher than in spontaneous vertex position, indicating that the breech position might have been an expression of fetopelvine distocia. <sup>54,61,70</sup> Given a 3% incidence of breech position at term and a 30%-40% success rate of ECV, one can calculate that ECV will lower overall CS rate by a maximum of 1%.

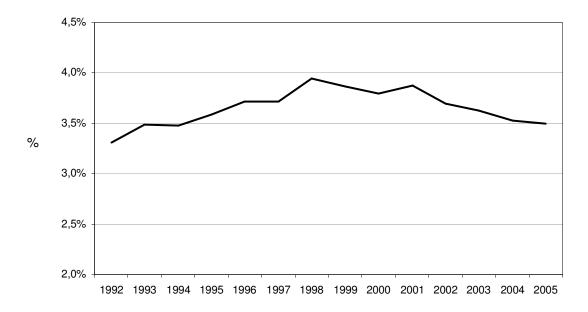


Figure 1. Percentage of term infants in breech at delivery, based on data from The Netherlands Perinatal Registry and data from the Central Statistics Office of The Netherlands (CBS).

In The Netherlands ECV was not performed as a standard procedure until 2000. Following the dramatic increase in CS rate of breech infants after the TBT, more attention has been given to ECV. Unfortunately, this item is not recorded in the Dutch Obstetric Registry and therefore it is not known whether more ECV's have been performed since 2000. Analysis of the number of term breech infants in The Netherlands shows a fluctuation between 3% and 4%, but no clear decline (figure 1) in percentage of breech since the change in policy, following publication of the TBT.

# Best practice of Evidence Based Medicine: observational studies versus randomised controlled trials

Since the eighties of the last century there is a rising interest in evidence based medicine (EBM), which is characterised by 'the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients'. The practice of evidence based medicine implies the integration of individual clinical expertise with the best external evidence available from systematic research. Together with this, the patient's wishes, preferences and expectations should play a key role in the decision making.

Even though randomised controlled trials (RCT) or systematic reviews are considered as the 'gold standard' for providing the best evidence and large RCT's are at the apex of the hierarchy, several other sources of evidence may inform clinical decision-making. <sup>71,72</sup>

Treating patients is not a simple process and evidence based medicine bears the risk of oversimplifying the complex nature of clinical care.<sup>73</sup> This leads to the unavoidable question whether RCT's and systematic reviews provide best evidence when applied to complex phenomena such as seen in obstetric care.<sup>3</sup>

Important limitations of RCT's are the amount of drop-outs, about which RCT's rarely give information. RCT's are known for their poor recruitment rate and most trials fail to report their rates. RCT's only provide us with information about groups, not individuals. The external validity of RCT's is often low, because either participating health care professionals are unrepresentative, the patients who participate may be atypical (motivated and cooperative participants might not be the typical cross-section of general patient population) or the given treatment may be atypical (better care for participating patients). Moreover, delivering a breech baby requires considerable skill and forms a discriminating obstetrical procedure. By randomisation, the relevance of poorly quantifiable clinical phenomena is obscured.<sup>3</sup> Systematic reviews of literature also have

their drawbacks, the most important being the publication bias (one cannot tell how many studies were conducted but never reported).

Because RCT's and systematic reviews do have their limitations in the complex matter of breech delivery, it is important to consider the complementary role of other sources of evidence, such as observational and large retrospective studies with previously selected patients. Shortcomings of observational methods are the fact that their internal validity may be undermined by previously unrecognised confounders which may not be evenly distributed accross intervention groups. And unfortunately, most register-based databases lack information on planned mode of delivery. Nevertheless, they do provide us with a large amount of data about the incidence of neonatal mortality and morbidity. T5-79

#### In conclusion

Planned CS is of advantage for the term infant in breech position. The procedure of performing external cephalic version does not have a direct advantage for the infant over a planned CS, but is of benefit to the mother and appears safe with an acceptable risk. The increase in CS will have detrimental consequences for future pregnancies and deliveries of the mother. This needs to be implicated in counselling the pregnant woman who bears a child in breech position. In this respect the young pregnant woman with future plans to expand offspring may well be counselled to have a vaginal delivery, whereas the woman who is older or otherwise is likely to end her reproductive career after this pregnancy, may be advised to have a CS.

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# 9

Nederlandstalige samenvatting

Hoofdstuk 9

#### **SAMENVATTING**

De meest gunstige positie bij de vaginale geboorte van een baby is de achterhoofdsligging, waarbij het foetale hoofd met de kleinste diameter het baringskanaal passeert. De schedel is het hardste gedeelte dat het baringskanaal en het moederlijke bekken moet passeren. Als er sprake is van een wanverhouding tussen benig deel van het bekken en het hoofd, dan zal dit bij een hoofdligging meestal blijken tijdens indaling en ontsluiting. Deze wanverhouding uit zich door een niet vorderende ontsluiting en indaling of uitdrijving. Is het hoofd onvoldoende ingedaald, dan is er in een dergelijke situatie in het algemeen voldoende tijd om over te gaan tot het verrichten van een keizersnede.

Bij 3% tot 4% van de voldragen kinderen ligt de baby in stuitligging. Dit kan een volkomen stuit zijn – het kind zit in kleermakerszit met de voetjes naar beneden of onder de billen – of een onvolkomen stuit, waarbij de voeten zijn opgeslagen tot naast het hoofd en de knietjes zijn gestrekt. In beide situaties zal het zachtere stuitgedeelte van de baby nu als eerste indalen en volgt als laatste de relatief grote benige schedel. Tijdens de geboorte kunnen zich verschillende problemen voordoen, die de mechanische passage bemoeilijken of in een zeldzaam geval onmogelijk maken. De armpjes kunnen opslaan, waarbij deze naast het foetale hoofd komen te liggen of er kan een wanverhouding zijn tussen de foetale schedel en het moederlijke bekken. In voorkomende situaties is vaak een groot gedeelte van het lichaam geboren voordat zo'n wanverhouding duidelijk wordt. Door middel van een gedeeltelijke stuitextractie, waarbij met verschillende soorten handgrepen het lichaam en het hoofd geboren worden, of een tang, kan assistentie geboden worden. Deze situatie gaat gepaard met een verhoogde kans op zuurstoftekort en op 'mechanische' schade van het kind, waarbij botbreuken, zenuwletsel en hoofdletsel de meest voorkomende zijn.

Om deze verhoogde kans op letsel bij de vaginale geboorte te voorkomen, wordt in toenemende mate gekozen om de baby in stuitligging via een geplande keizersnede geboren te laten worden. Hoewel ook dan de geboorte in stuitligging moeizaam kan verlopen, wordt veelal aangenomen dat de risico's veel kleiner zijn dan bij een vaginale geboorte.

In dit proefschrift wordt een aantal vragen beantwoord met betrekking tot de meest veilige manier van geboorte voor de voldragen foetus in stuitligging. Het keizersnede percentage bij stuitligging in Nederland is in de tijd langzaam gestegen tot 50% in 2000. In dat jaar werden de resultaten gepubliceerd van een groot onderzoek naar de beste wijze van geboorte bij een voldragen foetus in stuitligging, uitgevoerd in 121 centra in 26 landen: de

Samenvatting 121

'Term Breech Trial (TBT)'. Als gevolg van deze publicatie vond in Nederland in twee maanden tijd een dramatische stijging plaats van het percentage keizersnede van 50% tot 80%. Deze opvallende stijging leidde tot vele discussies over de validiteit van het onderzoek en over de vraag of een dergelijk buitenlands onderzoek wel toepasbaar is op de Nederlandse situatie. Aan dit onderzoek wordt dan ook in diverse hoofdstukken gerefereerd.

In **hoofdstuk 1** wordt een kort overzicht gegeven van de bestaande literatuur over de geboorte van de voldragen foetus in stuitligging en worden de doelstellingen van dit proefschrift uiteengezet. Hierbij komen de volgende vragen aan de orde:

- 1. Wat was de perinatale sterfte en morbiditeit in Nederland bij de verschillende wijzen van geboorte van het voldragen kind in stuitligging vóór de publicatie van de Term Breech Trial?
- 2. Wat was het effect van de TBT op het medisch handelen van de gynaecoloog en op de uitkomst van de kinderen in Nederland?
- 3. Welke factoren hebben bijgedragen tot de beleidsverandering onder de Nederlandse gynaecologen na de publicatie van de TBT?
- 4. Hoe hoog is momenteel het risico op perinatale sterfte en morbiditeit na vaginale (proef)baring of na een geplande keizersnede sinds de beleidsverandering, die optrad als gevolg van de publicatie van de TBT?
- 5. Wat is de verhouding jongens tot meisjes in stuitligging bij de geboorte in relatie tot de zwangerschapsduur?
- 6. Wat is het verband tussen stuitligging en verschillende aangeboren afwijkingen in relatie tot geslacht en zwangerschapsduur bij de geboorte?

In **hoofdstuk 2** worden perinatale sterfte en morbiditeit bij voldragen kinderen in stuitligging geanalyseerd in relatie tot de wijze van bevalling in de periode 1995 t/m 1999. Tot de publicatie van de TBT was er in Nederland een conservatief beleid aangaande de keizersnede bij voldragen stuitligging, resulterend in 75% vaginale proefbaring en totaal 50% vaginale baring. Voor de analyse werd gebruik gemaakt van gegevens uit de LVR-2 (Landelijke Verloskunde Registratie 2<sup>e</sup> lijn). Alle éénlingen in stuitligging tussen 37 en 42 weken werden geanalyseerd. Kinderen met aangeboren afwijkingen of sterfte voor de geboorte werden geëxcludeerd. In totaal konden 31.439 kinderen met een geboortegewicht kleiner dan of gelijk aan 4000g en 2385 kinderen met een geboortegewicht groter dan 4000g worden geanalyseerd. Vier verschillende wijzen van geboorte werden bestudeerd: geplande keizersnede vanwege stuitligging (electief),

122 Hoofdstuk 9

geplande keizersnede vanwege andere problematiek, spoed-keizersnede en vaginale baring. De laatste twee groepen werden gecombineerd tot één groep: geplande vaginale baring. Perinatale sterfte werd gedefinieerd als sterfte tijdens of gedurende 7 dagen na de geboorte. Perinatale morbiditeit werd gedefinieerd als een Apgar score bij 5 minuten kleiner dan 7 of trauma (hersenbloeding, zenuwletsel, botbreuken of ander trauma). Een logistische regressie analyse werd verricht om te bestuderen of bepaalde factoren, zoals geboortegewicht, zwangerschapsduur en pariteit (hoeveelste kind) elkaar beïnvloeden. Hieruit bleek dat alleen de factor geboortegewicht van invloed is op de uitkomst. Na een geplande keizersnede alleen vanwege de stuitligging bleek de kans op sterfte twee maal zo laag, de kans op een lage Apgar score zeven maal zo laag en de kans op geboortetrauma drie maal zo laag als na een geplande vaginale baring.

Om te onderzoeken of inleiding of bijstimulatie van de weeën leidt tot een verhoogde kans op problemen werd een aparte analyse uitgevoerd onder 16.884 bevallingen vóór 41 weken, waarbij geen weeënstimulerende middelen waren toegepast. Deze groep vertoonde geen betere resultaten en ook hier waren sterfte en morbiditeit significant hoger dan na een geplande keizersnede.

Om te onderzoeken of verschillen in plaatselijk beleid van invloed waren op de neonatale uitkomst werden alle 119 praktijken verdeeld in drie groepen volgens hun percentage geplande keizersnede. In alle groepen werden vergelijkbare resultaten gevonden. Problemen bij het nakomend hoofd (stagnatie) werden meer gezien naarmate de uitdrijvingsperiode langer was. Een tangverlossing bij problemen van het nakomend hoofd bleek geassocieerd te zijn met hogere sterfte, lagere Apgar score en meer trauma.

In hoofdstuk 3 wordt de enorme verandering in beleid beschreven na de publicatie van de TBT in oktober 2000. Het totale keizersnede percentage bij de voldragen stuitligging steeg in twee maanden van 50% tot 80%, voornamelijk door de stijging van de geplande (electieve) keizersnede. Hierna bleef het percentage stabiel. Deze stijging werd in vrijwel alle praktijken in Nederland in meerdere of mindere mate waargenomen. Om het effect te bestuderen dat deze verandering had op de neonatale uitkomst werden de resultaten van een periode van 33 maanden voor de TBT vergeleken met resultaten van een periode van 25 maanden erna. Gegevens werden verkregen van de Stichting Perinatale Registratie Nederland (PRN). In de analyse werden 35.453 voldragen éénling kinderen in stuitligging bestudeerd volgens dezelfde methode als in hoofdstuk 2. Na publicatie van de TBT en stijging van het keizersnede percentage bleek de perinatale sterfte significant te zijn gedaald van 0,35% naar 0,18%. Het percentage lage 5-minuten Apgar score daalde van 2,4% naar 1,1% en geboortetrauma van 0,29% naar 0,08%. Dit werd zowel voor

Samenvatting 123

kinderen met een geboortegewicht van minder dan of gelijk aan 4000g als groter gevonden. De daling in slechte perinatale uitkomst kan vooral worden toegeschreven aan de stijging van het aantal geplande (electieve) keizersneden. Zowel na een spoedkeizersnede als na een vaginale baring lijken de neonatale uitkomsten verbeterd, alhoewel statistisch geen significantie werd bereikt. Deze verbeterde uitkomst na een geplande vaginale baring zou kunnen betekenen dat de beslissing om toch een spoedkeizersnede uit te voeren eerder wordt genomen tijdens problemen bij de vaginale baring en dat sprake is van een betere risicoselectie.

De verandering in beleid heeft geresulteerd in ongeveer 2000 extra keizersneden op jaarbasis voor de voldragen stuitligging en met dit beleid sterven per jaar 11 kinderen minder dan voorheen. Met andere woorden: er worden 175 extra keizersneden verricht om 1 kind te sparen. Dit moet worden afgewogen tegen de toename op nadelige gevolgen voor de moeder, vooral bij volgende zwangerschappen (littekenscheur of placenta ingroei in de baarmoeder) met een verhoogd risico voor het toekomstige kind.

In **hoofdstuk** 4 is gebruik gemaakt van een koppeling van gegevens van de gynaecologen en de kinderartsen. Hiermee kan perinatale sterfte en ernstige neonatale morbiditeit in meer detail worden bestudeerd. Een analyse werd verricht onder 11.580 voldragen éénlingen in stuitligging, geboren in de periode 2001 t/m 2003. Kinderen met aangeboren afwijkingen en sterfte vóór de geboorte werden geëxcludeerd. Deelname aan de LVR-2 is vrijwel 100%; in de LNR (Landelijke Neonatale Registratie) neemt ongeveer 70% van de kinderarts-praktijken deel. Ernstige perinatale morbiditeit werd gedefinieerd als stuipen, hersenbeschadiging door zuurstoftekort, hersenbloedingen door trauma, botbreuken en zenuwletsel. Verder werden een 5-minuten Apgar score kleiner dan 4 en kleiner dan 7, hyperbilirubinaemie (geel zien) en longproblemen bestudeerd. Een logistische regressie analyse werd verricht om de invloeden van verschillende factoren, zoals geboortewijze, pariteit, zwangerschapsduur, geslacht en geboortegewicht te bestuderen. Geboortewijze werd op dezelfde wijze gedefinieerd als in eerdere hoofdstukken.

Het percentage kindersterfte tijdens en na de geboorte (tot 28 dagen of langer, indien opname langer duurde) was 0,38% in de groep geplande vaginale baring (vaginale baring plus spoedkeizersnede) vergeleken met 0% in de groep geplande keizersnede. Ernstige morbiditeit werd gezien bij 1,35% van de kinderen die vaginaal werd geboren en bij 0,48% na een spoedkeizersnede (totaal geplande vaginale baring 0,92%), terwijl dit 0,16% bedroeg na een geplande keizersnede. Het percentage sterfte en ernstige morbiditeit tezamen bedroeg na een geplande vaginale baring 1,29% en na een

124 Hoofdstuk 9

geplande keizersnede 0,16%, dus een verschil van meer dan 1%. Na bestudering in detail bleek dat sterfte vooral het gevolg was van zuurstoftekort rond de geboorte.

Longproblemen (zogenaamde 'natte long', waarbij vaak zuurstoftoediening en soms beademing noodzakelijk is) werden significant vaker gezien na een geplande keizersnede dan na een geplande vaginale baring. Dit bleek vooral te komen door een verhoogde incidentie na geplande keizersnede bij 37 en 38 weken.

Zowel een lage Apgar score, geel zien en de noodzaak tot reanimatie kwamen meer voor na een geplande vaginale baring.

Kleine kinderen (kleiner dan 2500g bij voldragen zwangerschap) hadden een significant hogere morbiditeit en mortaliteit na een vaginale baring dan kinderen met een normaal geboortegewicht. Dit werd bevestigd met logistische regressie analyse. Geen verschil werd gevonden voor de factoren geslacht, pariteit en zwangerschapsduur.

Concluderend draagt een geplande vaginale baring 1% meer risico op sterfte of ernstige morbiditeit dan een geplande keizersnede. Deze laatste zou beter niet kunnen worden uitgevoerd vóór 39 weken zwangerschap vanwege het verhoogde risico op longproblemen.

In hoofdstuk 5 worden de resultaten beschreven van een enquête, gehouden onder alle Nederlandse gynaecologenpraktijken. Met dit onderzoek werden de factoren bestudeerd die kunnen hebben bijgedragen tot de enorm snelle en plotselinge stijging van het keizersnede percentage bij de voldragen stuitligging na de publicatie van de TBT. De respons op de enquête was 86%. Op basis van een model werden vier invloeden bestudeerd: de invloed van de TBT zelf, van de patiënt, van de Nederlandse Vereniging van Obstetrie en Gynaecologie (NVOG) en van de professionele autonomie van de dokter. Er bleek een significante correlatie te bestaan tussen de invloed van de patiënt en de stijging van het keizersnede percentage. Uit het correlatie model en uit de antwoorden op de enquête, gegeven door de praktijken, kan het volgende worden geconcludeerd: de invloed van de patiënt, gestuurd door grote aandacht in de media voor de publicatie van de TBT en versterkt door de stimulatie van de NVOG om de onderzoeksresultaten met de patiënt te bespreken, lijkt de belangrijkste factor te zijn, die heeft geleid tot de verandering in beleid bij de voldragen stuitligging.

In **hoofdstuk 6** zijn de verschillen in geslacht van kinderen in stuitligging beschreven. Bij de algemene populatie – ongeacht de ligging – worden meer jongens dan meisjes geboren (51,5% jongens). Door gebruik te maken van gegevens van de LVR-2 werden 1,3 miljoen éénling kinderen geanalyseerd met een zwangerschapsduur van 24 t/m 42

Samenvatting 125

weken, geboren in de periode 1995 t/m 2003. Van deze groep lagen 70.125 kinderen bij de geboorte in stuit. Vanaf 31 weken worden significant meer meisjes in stuitligging geboren dan jongens. Bij 40 weken is slechts 43,4% van de kinderen in stuit een jongen. Het is bekend dat stuitligging bij de geboorte afhankelijk is van zwangerschapsduur en geboortegewicht. Foetaal geslacht blijkt tevens een onafhankelijke factor te zijn. De oorzaak van de overmaat aan meisjes is onbekend, maar zou te maken kunnen hebben met verschillen in grootte of vorm van het foetale bekken of de heupjes.

**Hoofdstuk 7** toont de resultaten van een analyse, verricht naar aangeboren afwijkingen bij kinderen in stuitligging. Het verhoogde risico op perinatale sterfte en morbiditeit onder kinderen in stuitligging is niet alleen te verklaren door een hogere frequentie van laag geboortegewicht, vroeggeboorte en traumatische geboorte. Ook aangeboren afwijkingen komen meer voor en dragen significant bij tot het sterfte-risico bij stuitligging. In de literatuur zijn voornamelijk kleinere studies beschreven met maximaal 2700 kinderen. Hierdoor is het moeilijk om de relatie van specifieke aangeboren afwijkingen met stuitligging te bestuderen. Door middel van gekoppelde bestanden van gegevens van de LVR-1 (verloskundigen, 1<sup>e</sup> lijn) en LVR-2 (gynaecologen, 2<sup>e</sup> lijn) over de periode 1996 t/m 2004, konden 1.620.246 éénling kinderen worden geanalyseerd. Hiervan werden er 78.133 in stuitligging geboren. Zeventig verschillende afwijkingen werden geanalyseerd en onderverdeeld in negen hoofdgroepen. Zowel de verschillen tussen stuit- en hoofdligging als de verschillen tussen jongens en meisjes werden geanalyseerd.

Van de kinderen in hoofdligging had 2,4% een aangeboren afwijking, terwijl dit percentage 4,4% bedroeg bij kinderen in stuitligging (bij jongens 2,9% versus 5,3% en bij meisjes 1,9% versus 3,7%). Een overmaat aan aangeboren afwijkingen bij stuitligging werd gevonden bij alle verschillende soorten afwijkingen en speciaal bij sluitingsdefecten van de neuraalbuis en afwijkingen van het centrale zenuwstelsel (ruggemerg en hersenen), het ademhalingssysteem, bewegingsapparaat (bot en spier) en bij kinderen met chromosomale, meervoudige en syndromale afwijkingen. Zowel bij vroeggeboren kinderen (32 t/m 36 weken) als bij voldragen kinderen (37 t/m 41 weken) werd deze overmaat onder kinderen in stuitligging gevonden, maar niet bij de zeer vroeg geboren kinderen (24 t/m 31 weken). Dit kan verklaard worden doordat bij een zeer vroege termijn 25%-40% van alle kinderen in stuit ligt en dit dus als een min of meer normale ligging mag worden beschouwd. Alle verschillende aangeboren afwijkingen op één na werden meer gevonden bij jongens dan bij meisjes; alleen neuraalbuisdefecten (open ruggetje) werden meer aangetroffen bij meisjes.

126 Hoofdstuk 9

Dat kinderen met aangeboren afwijkingen vaker in stuitligging worden geboren heeft meerdere oorzaken. Bij hydrocefalie (waterhoofdje) en neuraalbuisdefecten met soms grote vochtblazen, waarin zenuwweefsel ligt, spelen zowel mechanische factoren een rol, als ook de neurologische beperkingen die het kind door de afwijking heeft. Hierdoor kan het niet de juiste liggingspositie innemen. De overmaat aan afwijkingen van het ademhalingssysteem onder kinderen in stuitligging wordt verklaard door een overmaat aan longhypoplasie (onderontwikkeling van de longen). Deze afwijking is veelal niet door aanleg aanwezig, maar verworven door een tekort aan vruchtwater, vaak als gevolg van een ernstige nierafwijking of gebroken vliezen. Door het tekort aan vruchtwater kan het kind niet draaien.

Bij kinderen met chromosomale, meervoudige en syndromale afwijkingen zijn de foetale bewegingen nogal eens beperkt door een verlaagde of verhoogde spierspanning, met als gevolg dat de foetus niet de juiste positie inneemt.

In het onderzoek kwam een sterke correlatie naar voren tussen congenitale heupdysplasie (aangeboren heupje uit de kom) en stuitligging (tien maal zo vaak bij stuitligging). Deze correlatie is bekend uit de literatuur, net als de correlatie tussen heupdysplasie en het vrouwelijke foetale geslacht. Ook dit werd in onze studie gevonden. De oorzaak is onbekend.

Concluderend komen bij kinderen in stuitligging significant meer aangeboren afwijkingen voor. Jongetjes hebben anderhalf maal zo vaak afwijkingen als meisjes, zowel in hoofdals in stuitligging, behalve bij neuraalbuisdefecten en afwijkingen van het centrale zenuwstelsel, die meer bij meisjes voorkomen.

Hierbij is het belangrijk zich te realiseren dat de aangeboren afwijking zelf bijdraagt tot de stuitligging en niet andersom.

Tenslotte worden in **hoofdstuk 8** de bevindingen van het proefschrift samengevat. De belangrijkste conclusies zijn:

- Bij een beleid van 50% vaginale baring (zoals voorheen) bij de voldragen foetus in stuitligging zijn de risico's op perinatale sterfte en morbiditeit (lage Apgar score en trauma) hoger bij een geplande vaginale baring dan bij een geplande keizersnede.
- Geen subgroep kon worden gedefinieerd, waarbij een vaginale baring net zo veilig mag worden beschouwd als een geplande keizersnede.
- De zeer forse toename van 50% naar 80% keizersnede bij de voldragen stuit ging gepaard met een afname in sterfte tijdens en na de geboorte van 0,35% tot 0,18%.

Samenvatting 127

 Bij bestudering van de perinatale uitkomst aan de hand van gekoppelde gegevens van gynaecologen en kinderartsen, is de conclusie hetzelfde: de vaginale geboorte van het voldragen kind in stuitligging heeft een extra risico van meer dan 1% op perinatale sterfte of ernstige morbiditeit.

- Het is beter om een electieve geplande keizersnede niet vóór 39 weken zwangerschap te verrichten wegens het verhoogde risico op longproblemen bij een eerdere termijn, ook als dit inhoudt dat meer geplande keizersneden 's nachts zullen moeten worden verricht als gevolg van een spontaan begin van de baring voor de geplande operatiedatum.
- Vanaf 32 weken liggen meer meisjes in stuit dan jongens. Meisjes in stuitligging worden vaker vaginaal geboren dan jongens in stuitligging.
- Kinderen in stuitligging hebben significant vaker aangeboren afwijkingen dan kinderen in hoofdligging.
- Jongens hebben een anderhalf maal hogere kans op het hebben van een aangeboren afwijking dan meisjes, ongeacht de ligging, behalve bij neuraalbuisdefecten en afwijkingen van het centraal zenuwstelsel, die meer voorkomen bij meisjes.
- De toename van het aantal keizersneden bij de stuitligging trad in vrijwel alle Nederlandse praktijken op. Alhoewel 93% van de praktijken aangeeft dat de invloed van de TBT groot is geweest, vindt 60% dat de studie wetenschappelijk niet goed is onderbouwd of niet toepasbaar op de Nederlandse situatie.
- De invloed van de patiënt, gestuurd door grote aandacht in de media voor de resultaten van de TBT en versterkt door de stimulatie van de NVOG om de onderzoeksresultaten met de patiënt te bespreken, lijkt de belangrijkste factor te zijn, die heeft geleid tot de verandering in beleid bij de voldragen stuitligging.

In hoofdstuk 8 worden de implicaties van de keuze van de geboortewijze voor de foetus en de moeder besproken. De geplande keizersnede bij de voldragen stuit is van voordeel voor het kind, maar de keerzijde van de medaille is een toename van risico's bij een volgende zwangerschap en bevalling voor de moeder en toekomstige kinderen.

Consequenties voor het kind op de lange termijn zijn moeilijk te onderzoeken. In de literatuur zijn wisselende resultaten beschreven bij relatief kleine studiegroepen. Alhoewel niet zeker is hoe het met kinderen die bij de geboorte tekenen vertonen van ernstige schade, zal gaan op de kinderleeftijd en later, suggereren de resultaten in dit proefschrift sterk dat de vaginale stuitgeboorte een verhoogd risico met zich meebrengt op sterfte en blijvende handicaps.

Hoofdstuk 9

Daartegenover staan de directe en de lange termijn risico's voor de moeder van een keizersnede in vergelijking met een vaginale baring. Berekeningen met de Nederlandse cijfers, gecombineerd met cijfers over moedersterfte uit Groot-Brittannië, geven aan dat het directe risico op sterfte als gevolg van de keizersnede waarschijnlijk niet is verhoogd. Een toename van geplande keizersneden leidt tot een afname van spoedkeizersneden en die laatste zijn voor de moeder het meest riskant. Sinds 2000 zijn vijf sterfgevallen bekend (sinds 2000) van vrouwen die een keizersnede ondergingen bij een stuitligging. In drie van de vijf gevallen was sprake van bijkomende pathologie, waardoor van een electieve keizersnede geen sprake was. Hoewel iedere moedersterfte bijzonder ernstig is, is het aantal te klein om te concluderen dat het directe sterfterisico hoger is door toename van geplande keizersneden.

De lange termijn risico's zijn wel een reden tot zorg. Bij een volgende zwangerschap en vaginale baring na een eerdere keizersnede is het risico op openscheuren van het litteken in de baarmoeder verhoogd. Ook het risico op een ingegroeide placenta is verhoogd, met mogelijk ernstige consequenties zoals massaal bloedverlies of de noodzaak tot het verwijderen van de baarmoeder. Dit laatste gaat gepaard met een verhoogd risico op moedersterfte. Het inleiden van de baring met prostaglandines verhoogt het risico op het openscheuren van het litteken in de baarmoeder.

Bij het opmaken van de balans kan dus het volgende worden gesteld: per jaar worden met het nieuwe beleid 2000 extra keizersneden verricht. Dit spaart het leven van 11 kinderen in stuitligging. Voor de Nederlandse vrouw is de kans op een volgende zwangerschap ongeveer 50%. Dit betekent dat 1000 extra zwangere vrouwen zullen terugkomen met een litteken in de baarmoeder. Het te voeren beleid ten aanzien van de baring na een voorgaande keizersnede is nog steeds een onderwerp van discussie. Verschillende onderzoeken wijzen uit dat het risico van een vaginale baring na een voorgaande keizersnede laag is en een vaginale baring een verantwoorde optie is, waarmee het nog altijd stijgende keizersnedepercentage kan worden beperkt. Op basis van eerder onderzoek is bekend dat in Nederland 72% van de vrouwen met een voorgaande keizersnede een geplande vaginale baring ondergaat. Ook is in Nederlands onderzoek gevonden dat het risico bij een dergelijke situatie op een scheuring in het oude litteken van de baarmoeder 1,5% bedraagt. Dit resulteert in 10 van de 1000 vrouwen met een scheuring in het oude litteken, met als gevolg 1 perinatale sterfte van een kind. De 'netto winst' van het nieuwe beleid is dus niet 11 maar 10 kinderen.

Onder de 1000 extra zwangeren met een litteken in de baarmoeder zal tien maal een baarmoederscheur optreden en drie maal een spoedoperatie ter verwijdering van de

Samenvatting 129

baarmoeder. De moedersterfte is hoog bij deze ingreep (4%). Als men op basis van deze cijfers doorrekent, betekent dit dat voor elke 80 'geredde' kinderen (ofwel eens in de 8 jaar) één moeder sterft.

Het door middel van manipulatie uitwendig draaien (versie) van de stuitligging is een veilige procedure en kan een bijdrage leveren aan de daling van het aantal kinderen in stuitligging en daarmee van het aantal uitgevoerde keizersneden. Het te vroeg uitvoeren van versie (voor 34 weken) is niet zinvol, aangezien dit niet leidt tot een afname van het aantal voldragen kinderen in stuit. Complicaties als gevolg van versie voor moeder en kind zijn zeldzaam. Een vertraging van de foetale hartslag is meestal voorbijgaand. Een enkele keer herstelt de hartslag niet en moet een spoedkeizersnede worden verricht. In Nederland lijkt de aandacht voor uitwendige versie sinds de TBT te zijn toegenomen. Het percentage stuitligging is echter sinds de TBT nog niet gedaald en fluctueert tussen 3% en 4%.

Concluderend is een geplande keizersnede van voordeel voor het kind in stuitligging. De keerzijde van de medaille is echter een toename van risico op moedersterfte en morbiditeit, zoals een ernstige bloeding of verwijdering van de baarmoeder bij een volgende baring na keizersnede. De 'reproductieve' toekomstplannen van de zwangere met een kind in stuitligging zullen bij de counseling ten aanzien van de wijze van geboorte moeten worden betrokken.

## List of co-authors

132 List of co-authors

S. Anthony, PhD. Department of Reproduction and Perinatology, TNO Quality of Life, Leiden, The Netherlands.

- R. Brand, PhD. Department of Medical Statistics & BioInformatics, University Medical Centre, Leiden, The Netherlands.
- H.W. Bruinse, MD, PhD. Department of Perinatology and Gynaecology, University Medical Centre, Utrecht, The Netherlands.
- P.M. Elferink-Stinkens, PhD. Department of Medical Informatics, Erasmus University Medical Centre, Rotterdam, The Netherlands.
- M.J. Faber, PhD. Centre for Quality Of Care Research, Radboud University Medical Centre, Nijmegen, The Netherlands.
- F. Groenendaal, MD, PhD. Department of Neonatology, University Medical Centre, Utrecht, The Netherlands.
- R. Grol, PhD. Centre for Quality Of Care Research, Radboud University Medical Centre, Nijmegen, The Netherlands.
- O.J.S. Van Hemel, MD, PhD. Department of Obstetrics and Gynaecology, Reinier de Graaf Hospital, Delft, The Netherlands.
- A.J. van Loon, MD, PhD. Department of Obstetrics and Gynaecology, Martini Hospital, Groningen, The Netherlands.
- Y. Schönbeck, MSc. Department of Reproduction and Perinatology, TNO Quality of Life, Leiden, The Netherlands.
- G.H.A. Visser, MD, PhD. Department of Perinatology and Gynaecology, University Medical Centre, Utrecht, The Netherlands.

# Dankwoord

134 Dankwoord

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Curriculum Vitae 135

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136 Dankwoord

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## Curriculum Vitae

138 Curriculum Vitae

Christine Rietberg werd als tweede in een gezin van drie kinderen geboren op 16 december 1965 te Dordrecht. Zij groeide op in Zwijndrecht en behaalde in 1984 haar diploma atheneum B aan het Develstein College in Zwijndrecht. In datzelfde jaar startte zij in Rotterdam de studie geneeskunde aan de Erasmus Universiteit, initieel gecombineerd met het eerste jaar hoofopleiding piano aan het Conservatorium in Rotterdam. Al vanaf de doctoraalstudie was haar bijzondere interesse in de gynaecologie en verloskunde gewekt. Een zeven maanden durende onderzoeksstage in Denver -Colorado in 1990 over basaal foetaal eiwit-metabolisme in het schaap versterkte verder deze belangstelling. In 1992 haalde zij haar artsenbul en na een academische AGNIOperiode in Rotterdam startte zij in 1994 de opleiding tot gynaecoloog. Deze werd grotendeels gevolgd in het Ikazia ziekenhuis Rotterdam met als opleider M.E. Vierhout en in het Erasmus MC (voorheen Dijkzigt ziekenhuis) met als opleiders de hoogleraren A.C. Drogendijk, H.C.S. Wallenburg en Th.J.M. Helmerhorst. De opleiding werd beeindigd in het Reinier de Graaf Gasthuis (opleider J.C. Kuijpers). Sinds 2002 is zij in een vakgroep van zeven als gynaecoloog werkzaam in het Vlietland ziekenhuis, locatie Vlaardingen. Zij is getrouwd met Oscar Van Hemel en heeft drie dochters, Leonie (1996), Cecile (1996) en Claire (1998).

# List of publications

140 List of publications

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List of publications 141

## Submitted for publication

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Rietberg CC, Anthony S, Schönbeck Y, Visser GH. Congenital malformations among infants in breech position: a study of 1.4 million newborns.

