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

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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 ≤ 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 ≤ 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)[1] 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.[2] 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[3] and in The Netherlands the overall CS rate of term breeches increased from 50% in 2000 to 80% in 2001.[4]

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.[5] 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[6] 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.[7-10]

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.[11,12]
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.

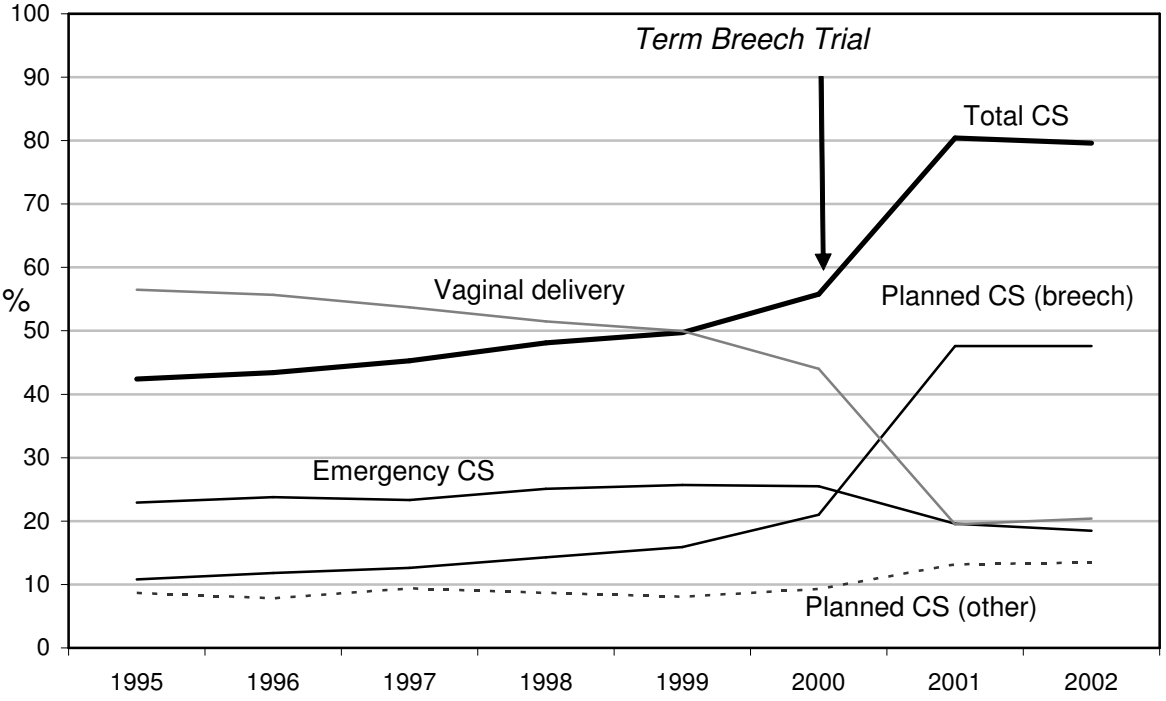

Figure 1. Trends in vaginal delivery and caesarean section in women with a term singleton infant in breech presentation between 1995 – 2002.

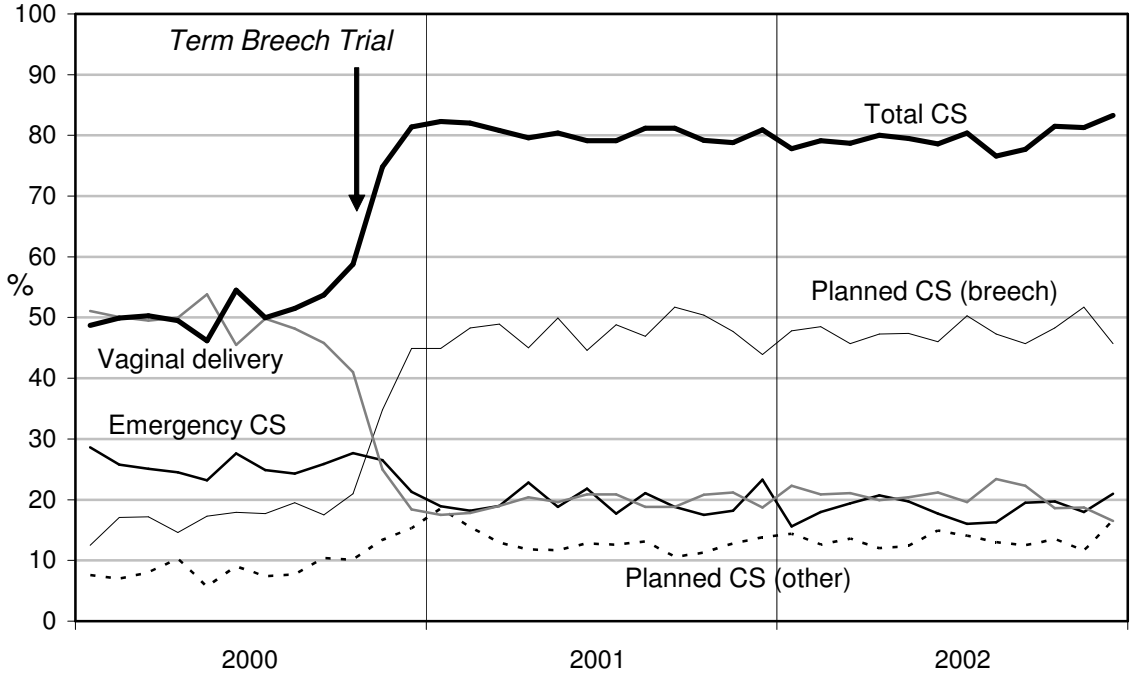

Figure 2. Percentages of different modes of delivery in women with a term singleton infant in breech presentation preceding and following the publication of the Term Breech Trial in October 2000.

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)	*p*
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 ≤ 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 ≤ 4000g. Values are given in *n* (%).

	Planned CS (breech)		Planned CS (other)		Emergency CS		Vaginal delivery	
TBT	**before**	**after**	**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.[13-16] 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

* 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,[17] especially uterine rupture[18-22] and placental invasion of the uterine scar during subsequent pregnancies.[23-28]

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