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,a Patty M. Elferink-Stinkens,b Gerard H.A. Visserc

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

Design Retrospective observational study.

Setting The Netherlands.

Population Infants born at term in breech presentation in the Netherlands between 1998 and 2002, with birthweights ≤4000 g (n = 33,024) and >4000 g (n = 2429), respectively. Multiple pregnancies, antenatal death and major congenital malformations were excluded.

Methods Data derived from the Dutch Perinatal Database were 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 ≤4000 g, this was associated with a significant decrease of perinatal mortality from 0.35% to 0.18%, a decrease of the incidence of a 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 >4000 g, 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 was followed by improved neonatal outcome.

INTRODUCTION

In October 2000, the results of the Term Breech Trial1 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 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 six 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 up to and including 1999.2 Vaginal delivery and emergency caesarean section resulted in a sevenfold increase in low 5-minute Apgar score, a threefold increase in birth trauma and a twofold increase in perinatal death when compared with the results of planned caesarean section, thus confirming the results of the Term Breech Trial.

Publication of the Term Breech Trial has resulted in an increase of planned caesarean section in centres that took part in this trial3 and in the Netherlands the overall caesarean section 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 and 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 Verloskundige Registratie-2; LVR-2) was set up in 1982 for all secondary care obstetric departments. This set up was preceded 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 data. This preliminary registry was extensively investigated and validated. Computerised error checks strongly improved the validity of the system 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.

In the LVR-2, the indications for planned caesarean section (i.e. with no intended trial of labour) is registered for every patient in this category. The indications are subdivided in the following categories: ‘elective’, ‘due to the condition of the mother’, ‘of the fetus’, ‘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 caesarean section due to breech position only, without additional pathology. In 0.4% of cases, the mode of delivery was not coded. Comparison of the planned caesarean section due to breech position only group, with the combined vaginal delivery and emergency caesarean section during labour subgroups (i.e. planned vaginal delivery group), may reveal differences in outcome according to the chosen policy, as was done in our retrospective population-based study.

In order to enable comparison with the data of the Term Breech Trial, we included infants in breech presentation who were delivered at term (between 37 and 42 weeks of gestation) with birthweights ≤4000 g as we did in our previous study. Exclusion criteria were multiple pregnancy, antenatal fetal death and major congenital malformations (central nervous system abnormalities, such as spina bifida, meningomyelecele, 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 birthweight >4000 g.

Outcome measures were Perinatal death: this was defined as intrapartum death or death within a week following birth.

Five-minute Apgar score: the Apgar score was subdivided as either <7 or ≥7, according to reports from Sweden and Norway on prediction of long term neonatal morbidity.

Neonatal trauma: this was classified as intracerebral bleeding, cephalic haematoma, facial nerve paresis, 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 Term Breech Trial 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 Term Breech Trial started at 1st December 2000 and included the
years 2001 and 2002. For trend analysis of vaginal delivery and caesarean section rate, data from 1995 till and including 2002 were taken.

RESULTS

Figure 1 shows the trends in vaginal delivery and caesarean section 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 Term Breech Trial, there was an increase in total caesarean section rate from 50% to over 80% and this rate has remained stable thereafter. This rise was mainly due to an increase in planned caesarean section. Emergency caesarean section decreased slightly.

The increase in caesarean section rate after publication of the Term Breech Trial was observed in all but three hospitals in the Netherlands and the proportional increase in caesarean section rate was more or less similar in those hospitals with an initial low or high caesarean section rate.

Table 1 shows neonatal outcome following term breech delivery in the Netherlands in infants weighing ≤4000 g in the 33 months before publication of the Term Breech Trial and in the 25 months thereafter. There was a twofold decrease in perinatal death and in low 5-minute Apgar score and an almost fourfold decrease in neonatal trauma.

This decrease can mainly be attributed to the increase in planned caesarean section because of breech position, as this mode of delivery was associated with the lowest mortality and morbidity, both before and after the Term Breech Trial (Table 2). After the publication of the Term Breech Trial, the neonatal outcome after emergency caesarean section also seemed to be 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 Term Breech Trial did not reach statistical significance (Table 2).

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

This study has shown that the caesarean section rate for babies at term with breech presentation in the Netherlands was increased from 50% to 80% within two months after publication of the Term Breech Trial. This increase in caesarean section rate occurred in almost all Dutch hospitals. This change in policy was associated 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 behaviour 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 Term Breech Trial 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 Term Breech Trial to change practice.

The Term Breech Trial 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 caesarean section, but outcome was also slightly better following emergency caesarean section and vaginal delivery. This may indicate that the decision to perform an emergency caesarean section was made earlier after the Term Breech Trial 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 caesarean section.

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

An increase in caesarean section 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 maternal morbidity and mortality due to the caesarean section and an increased maternal and fetal risk in subsequent pregnancies especially uterine rupture and placental invasion of the uterine scar during subsequent pregnancies.

References


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