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Outcomes of children at 2 years after planned cesarean birth versus planned vaginal birth for breech presentation at term: The International Randomized Term Breech Trial

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KEY WORDS
Cesarean delivery
Breech presentation
Infant

Objective: The purpose of this study was to determine whether planned cesarean delivery for the singleton fetus in breech presentation at term reduces the risk of death or neurodevelopmental delay at 2 years of age.

Study design: In selected centers in the Term Breech Trial, children were screened for abnormalities at ≥ 2 years of age with the Ages and Stages Questionnaire, followed by a neurodevelopmental assessment if the Ages and Stages Questionnaire score was abnormal.

Results: A total of 923 of 1159 children (79.6%) from 85 centers were followed to 2 years of age. The risk of death or neurodevelopmental delay was no different for the planned cesarean than for the planned vaginal birth groups (14 children [3.1%] vs 13 children [2.8%]; relative risk, 1.09; 95% CI, 0.52- 2.30; $P = .85$; risk difference, +0.3%; 95% CI, −1.9%, +2.4%).

Conclusion: Planned cesarean delivery is not associated with a reduction in risk of death or neurodevelopmental delay in children at 2 years of age.

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Babies who are born at term in breech presentation have been reported to have poorer outcomes than babies who are born in cephalic presentation.[1,2] Some analyses of observational studies have found that delivery by elective cesarean delivery reduces the risk of long-term adverse outcomes for children who born at term in breech presentation.[3,4] However, in 1996, a large population-based follow-up study of term breech infants found similar outcomes at 4 to 5 years of age for children who were delivered by elective cesarean delivery compared with those children who were delivered vaginally or by emergency cesarean delivery.[5]

The Term Breech Trial, a multicenter international randomized controlled trial of 2088 women with a singleton fetus in breech presentation at term, found a significant reduction in the risk of perinatal or neonatal death or serious neonatal morbidity during the first 6 weeks of life (1.6% vs 5.0%; $P < .0001$) with planned cesarean birth, compared with planned vaginal birth.[6] Adverse outcomes in the early neonatal period may not translate into adverse outcomes later in life. To date, no randomized study of term breech delivery has followed infants beyond the neonatal period. The Term Breech Trial, which avoided selection bias because of randomization, provided a unique opportunity to assess the effects of a policy of planned cesarean birth compared with planned vaginal birth on outcomes of children at 2 years of age. Specifically we wished to determine whether a planned cesarean delivery reduced the risk of death or subsequent neurodevelopmental delay at 2 years of age.

Material and methods

Eligibility and randomization

Women were eligible for the trial if they had a singleton live fetus in a frank or complete breech presentation at term ($\geq$ 37 weeks gestation). The study was approved by the research ethics committees at participating centers, and women gave informed consent before being enrolled in the study. Eligible and consenting women were then allocated randomly, with a centralized randomization service, to either the planned cesarean or the planned vaginal birth groups. Babies in breech presentation who were delivered vaginally were attended by a clinician who was experienced in vaginal breech delivery. The details of the eligibility criteria and treatment protocol have been published previously.[6] Centers that were confident in their ability to trace >80% of the randomly assigned women followed the children to $\geq$2 years of age.

Follow-up and outcomes

When the child reached 23 to 25 months of age, parents were asked to complete an Ages and Stages Questionnaire (ASQ).[7] The ASQ is a parent-administered structured questionnaire that includes questions on 5 domains of child development: communication, gross motor skills, fine motor skills, problem-solving skills, and person-social skills. The scores for each domain are summed, and if the score for any 1 of the 5 domains is abnormal, the ASQ is considered to be abnormal. The ASQ has been validated against the Bayley Scales of Infant Development and at 24 months has a reported sensitivity of 97.5% and a specificity of 79.3%.[7] If the ASQ could not be completed between 23 and 25 months of age, mothers were asked to complete a 30-month ASQ at 29 to 31 months.

If the ASQ score was abnormal or not done, a neurodevelopmental assessment was undertaken by a trained professional. The primary outcome for the 2-year follow-up of the children was death at any time after randomization or neurodevelopmental delay.

Statistical analysis

The results were analyzed according to intention to treat. Children with lethal congenital anomalies or Down syndrome, which were determined masked to allocation group, were excluded from the analyses. The groups were compared with Fisher's exact test for the analysis of binary outcomes and the Wilcoxon's rank-sum test for the analysis of continuous variables that were not distributed normally. A 2-sided probability value of <.05 was considered to indicate statistical significance. Relative risks, risk differences, and their 95% confidence intervals were also calculated. The analyses were undertaken with SAS software system (version 8.0; SAS Institute Inc, Cary NC).

We undertook 1 descriptive subgroup analysis of the primary outcome, not planned as part of the original protocol, for children who were born in countries with low (<20/1000 births) and high (>20/1000 births) national perinatal mortality rates as defined by the World Health Organization in 1996.[8] Countries with low national perinatal mortality rates were Australia, Canada, Chile, Denmark, Germany, Israel, the Netherlands, New Zealand, Poland, Portugal, Romania, Switzerland, the United Kingdom, and the United States. Countries with high national perinatal mortality rates were Argentina, Brazil, Jordan, and Pakistan.

Results

The Term Breech Trial enrolled 2088 women between January 9, 1997, and April 21, 2000, at 121 centers in 26 countries. In 85 centers in 18 countries, 1159 (55.5%) children participated in the 2-year follow-up, of which 580 children were assigned to the planned cesarean birth group, and 579 children were assigned to the planned vaginal birth group (Figure). We received follow-up

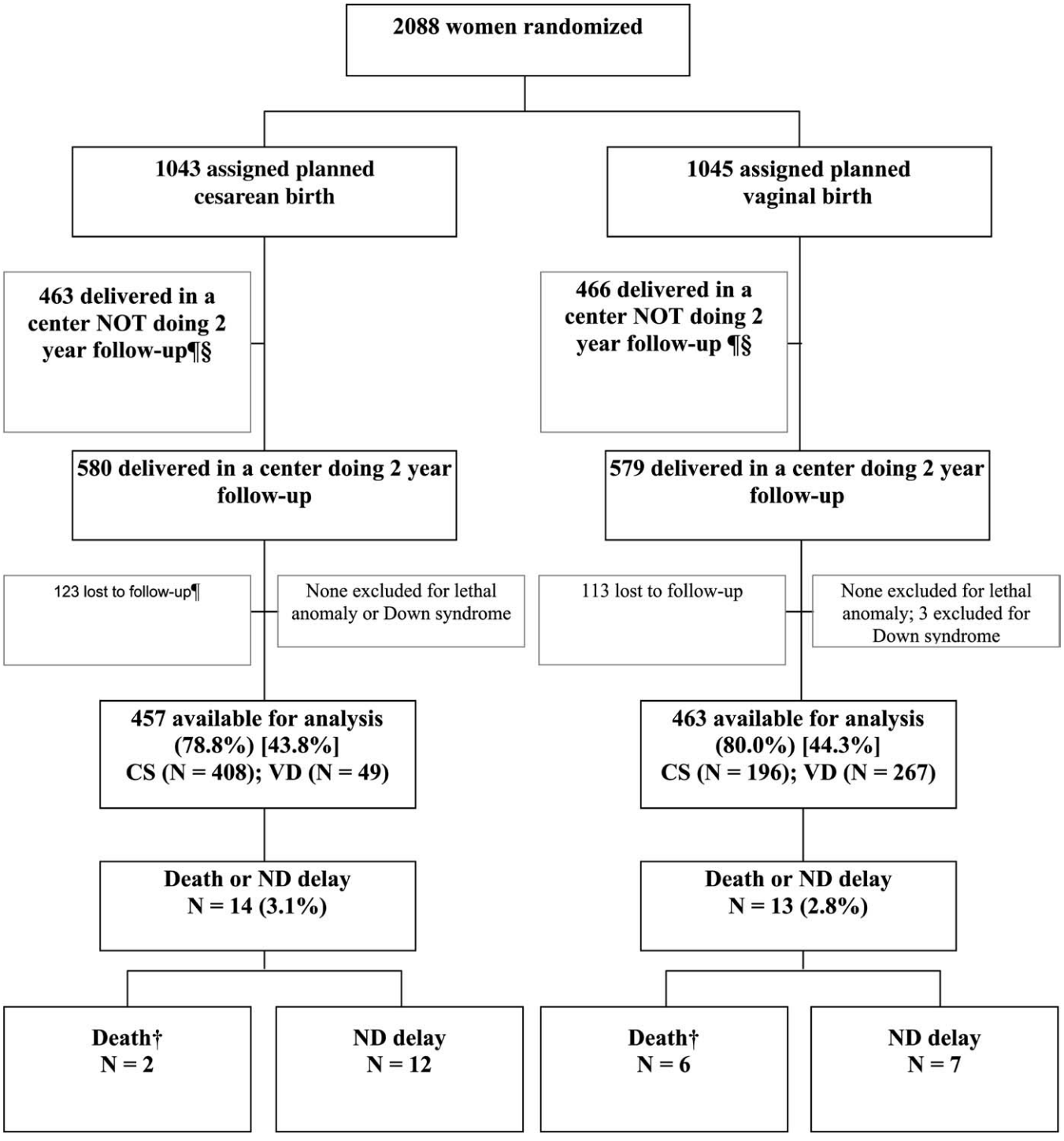

Figure Trial profile. The *paragraph symbol* indicates the inclusion of 1 woman in the planned cesarean birth group and 3 women in the planned vaginal birth group who were lost to follow-up in the main trial. The *double S symbol* indicates that 3 infants in the planned cesarean birth group died (2 deaths were at <28 days of age and were reported as part of the primary outcome of the main trial[6]; 1 death was at >28 days of age) and that 8 infants in the planned vaginal birth group died (8 deaths were at <28 days of age and were reported as part of the primary outcome of the main trial[6]; none of the deaths were at >28 days of age). The *cross symbol* indicates the planned cesarean birth group: 1 death was at <28 days of age and was reported as part of the primary outcome of the main trial,[6] and 1 death was at >28 days of age. In the planned vaginal birth group, 5 deaths were at <28 days of age and were reported as part of the primary outcome of the main trial,[6] and 1 death was at >28 days of age. *CS*, Cesarean delivery; *VD*, vaginal delivery; *ND*, neurodevelopmental delay.

information for 923 of these children (79.6%), of which 457 children were in the planned cesarean birth group and 466 children were in the planned vaginal birth group (Figure). Three children in the planned vaginal birth group were excluded from further analyses because of Down syndrome.

Baseline characteristics, mode of delivery, and initial perinatal/neonatal outcomes

Those women who were delivered in centers that participated in the 2-year follow-up evaluation were somewhat more likely to have been ≥30 years of age and to have been born in a country with a low national perinatal mortality rate and were somewhat less likely to have been nulliparous than the women who were enrolled originally in the Term Breech Trial (Table I).

The rate of cesarean births in the planned cesarean birth group was similar for women who were followed (89.3%), compared with all those women who were enrolled in the Term Breech Trial (90.4%). The rate of vaginal delivery in the planned vaginal birth group was also similar for women who were followed (57.7%), compared with all those women who were enrolled in the Term Breech Trial (56.7%).

For the children followed to ≥2 years of age, mothers in the planned cesarean birth group were somewhat less likely to have been nulliparous (44.9% vs 48.8%) or to have been in labor at the time of randomization (36.5% vs 44.1%) than those in the planned vaginal birth group. Otherwise, baseline characteristics were fairly similar in the 2 randomized groups (Table I).

Of the 24 infants with serious neonatal morbidity who were born in centers that participated in the 2-year follow-up evaluation, we received outcome information for 18 infants (4 infants were in the planned cesarean birth group, and 14 infants were in the planned vaginal birth group). The types of serious neonatal morbidity that were experienced by these children are detailed in Table I.

Death after 28 days of age in children who underwent follow-up evaluation

Two children died after 28 days of age. One child was in the planned cesarean birth group. She died at 21 months of age after cardiac surgery for a complex cardiac anomaly. The child had been delivered by prelabor cesarean delivery, weighed 3220 g at birth, had Apgar scores of 9 and 10 at 1 and 5 minutes, respectively, and had had no neonatal problems. The second child was in the planned vaginal birth group. She died at 42 months of age from overwhelming group A Streptococcus infection after surgery for subglottic stenosis, which was thought to be congenital in origin. This child had been delivered vaginally in frank breech presentation, weighed 2835 g at birth, and had had serious neonatal morbidity in the first 6 weeks of life, which consisted of a 5-minute Apgar score of 3, a cord blood base deficit of 20.0 mmol/L, seizures at 2 hours of age and needed 2 drugs to control them, was intubated and ventilated at birth, and had tube feeding for 18 days.

ASQ

Most of the surviving children had an ASQ completed either at 24 months (357/455 children [78.5%] in the planned cesarean birth group; 382/457 children [83.6%] in the planned vaginal birth group) or at 30 months (58/455 children [12.7%] in the planned cesarean birth group; 46/457 children [10.1%] in the planned vaginal birth group; Table II). The ASQ scored in the abnormal range for 40 of 415 children (9.6%) in the planned cesarean birth group and for 38 of 428 children (8.9%) in the planned vaginal birth group (relative risk, 1.09; 95%CI, 0.71-1.66; $P = .72$). The groups did not differ with respect to the risk of an abnormal score for any of the individual domains (Table II). Children in the planned cesarean birth and planned vaginal birth groups did not differ with respect to most other questions on the ASQ, but more parents in the planned cesarean birth group than the planned vaginal birth group reported that their children had had medical problems in the past several months (86/413 children [20.8%] vs 63/426 children [14.8%]; relative risk, 1.41; 95%CI, 1.05-1.89; $P = .02$). The types of medical problems did not differ between groups.

Death or neurodevelopmental delay

A neurodevelopmental assessment was undertaken for 80 of 455 surviving children in the planned cesarean birth group (17.6%) and 67 of 457 children in the planned vaginal birth group (14.7%), either because the ASQ was abnormal or because the ASQ was not done. For these children, the median age for completion of the neurodevelopmental assessment was 27.1 months (5th, 95th percentile, 22.8, 38.2) in the planned cesarean birth group and 27.2 months (5th, 95th percentile, 23.7, 38.8) in the planned vaginal birth group. Nineteen children had neurodevelopmental delay, 12 of 80 children (15.0%) in the planned cesarean birth group and 7 of 67 children (10.4%) in the planned vaginal birth group. Twelve of these children had a 3-month developmental delay or suspect neurologic examination; the other 7 children had a gross developmental delay or an abnormal neurologic examination (Table III).

The risk of death or neurodevelopmental delay was not different between the planned caesarean birth group (14/457 children [3.1%]) and the planned vaginal birth group (13/463 children [2.8%]; relative risk, 1.09; 95%

Table I Characteristics at randomization and initial perinatal/neonatal outcomes for all infants and for infants who received follow-up evaluations (excluding infants with Down syndrome)

Characteristic	All infants in both groups: N = 2083 (n)*	Infants followed (n)	
		Planned cesarean birth (N = 457)	Planned vaginal birth (N = 463)
Maternal age ≥30 y	670 (32.2%)	181 (39.6%)	184 (39.7%)
Nulliparity	1092 (52.4%)	205 (44.9%)	226 (48.8%)
Type of breech presentation			
Frank	1292 (62.0%)	299 (65.4%)	296 (63.9%)
Complete	702 (33.7%)	134 (29.3%)	149 (32.2%)
Uncertain	89 (4.3%)	24 (5.3%)	18 (3.9%)
In labor at randomization	890 (42.7%)	167 (36.5%)	204 (44.1%)
Membranes ruptured at randomization	486 (23.3%)	85 (18.6%)	99 (21.4%)
Previous cesarean delivery	54 (2.6%)	13 (2.8%)	8 (1.7%)
Perinatal mortality rate in country†			
Low (≤20/1000)	1027 (49.3%)	263 (57.5%)	259 (55.9%)
High (>20/1000)	1056 (50.7%)	194 (42.5%)	204 (44.1%)
Married/stable relationship	1943 (93.3%)	442 (96.7%)	444 (95.9%)
Planning to breast feed			
Yes	1848 (88.7%)	395 (86.4%)	407 (87.9%)
No	107 (5.1%)	27 (5.9%)	29 (6.3%)
Unknown or undecided	128 (6.1%)	35 (7.7%)	27 (5.8%)
Perinatal or neonatal death at <28 d	16/2078 (0.8%)‡	1 (0.2%)	5 (1.1%)
Serious neonatal morbidity§	53/2062 (2.6%)	4/456 (0.9%)	14/458 (3.1%)
Types of serious neonatal morbidity§			
Birth trauma	14 (0.7%) [7]‖	0 [0]	4 [1]¶
Seizures (at <24 hours of age or requiring ≥2 or more drugs to control)	7 (0.3%) [4]	0 [0]	2 [2]
Hypotonia for ≥2 hours	13 (0.6%) [10]	0 [0]	5 [4]
Stupor, decreased response to pain, or coma	3 (0.1%) [3]	0 [0]	3 [3]
5-Min Apgar score, <4	10 (0.5%) [5]	0 [0]	2 [2]
Cord blood base deficit ≥15	17 (0.8%) [6]	2 [0]	6 [4]
Intubation and ventilation >24 hr	5 (0.2%) [5]	0 [0]	3 [3]
Tube feeding for ≥4 d	8 (0.4%) [5]	1 [1]	4 [2]
Care in neonatal intensive care unit for >4 d	10 (0.5%) [8]	2 [1]	3 [3]

* Five women were lost to follow-up in the main trial; 1 of these women was enrolled in a center that did the 2-year follow-up.

† National perinatal mortality rate as reported by the World Health Organization[8]: countries with a low perinatal mortality rate were Australia, Canada, Chile, Denmark, Germany, Israel, the Netherlands, New Zealand, Poland, Portugal, Romania, Switzerland, the United Kingdom, and the United States; countries with a high perinatal mortality rate were Argentina, Brazil, Jordan, and Pakistan.

‡ For all infants, 2 infants with lethal anomaly in the planned cesarean birth group and 3 infants with lethal anomaly in the planned vaginal birth group were excluded from analyses (there were no cases of lethal anomaly among those who had a follow-up evaluation).

§ Deaths were excluded from the analysis of measures of serious neonatal morbidity.

‖ Data in brackets indicate the number of babies who had this specific morbidity plus ≥1 other serious neonatal morbidity.

¶ Two infants had significant genital injury, and 2 infants had peripheral nerve injury present at discharge from hospital in the planned vaginal birth group.

CI, 0.52-2.30; $P = .85$; risk difference, +0.3%; 95% CI, −1.9%, +2.4%; Table III). The risk of death or neurodevelopmental delay was somewhat higher for children who were born in countries with low (vs high) national perinatal mortality rates; however, the rates did not differ between the planned cesarean birth and planned vaginal birth groups for the different types of countries (P value for interaction, .66; Table III). One of the 18 children with serious neonatal morbidity in the first 6 weeks of life died of complications after surgery for subglottic stenosis, which was thought to be congenital in origin. The other 17 children had no evidence of neurodevelopmental delay at follow up.

Comment

This is the first report of a randomized controlled trial that compares the policies of planned cesarean birth and planned vaginal birth for breech presentation at term in

Table II ASQ, excluding deaths and infants with Down syndrome

Outcome	Planned cesarean birth (n = 415)	Planned vaginal birth (n = 428)	Relative risk (95% CI)	*P* value
ASQ completed (n)*				
At 24 mo	357 (86.0%)	382 (89.3%)		
At 30 mo	58 (14.0%)	46 (10.7%)		
Median age of child at completion (mo; 5th, 95th percentile)	24.3 (23.1, 30.6)	24.2 (23.0, 30.1)		
Person completing the questionnaire†				
Mother	392 (94.9%)	396 (93.4%)		
Father	18 (4.4%)	19 (4.5%)		
Other	3 (0.7%)	9 (2.1%)		
Help with the completion of the questionnaire†	250 (60.4%)	269 (63.1%)		
Doctor or nurse from the hospital	180	200		
Spouse/partner	57	62		
Other help	19	15		
No help with the completion of the questionnaire	164 (39.6%)	157 (36.9%)		
Abnormal ASQ ($\geq$1 abnormal scores)	40 (9.6%)	38 (8.9%)	1.09 (0.71-1.66)	.72
Abnormal communication score‡,§	12 (2.9%)	10 (2.3%)	1.24 (0.54-2.83)	.67
Abnormal gross motor score‡,‖	10 (2.4%)	6 (1.4%)	1.72 (0.63-4.69)	.32
Abnormal fine motor score‡,¶	15 (3.6%)	15 (3.5%)	1.03 (0.51-2.08)	1.00
Abnormal problem-solving score‡,#	11 (2.7%)	16 (3.7%)	0.71 (0.33-1.51)	.44
Abnormal personal-social score‡	20 (4.8%)	15 (3.5%)	1.38 (0.71-2.65)	.39
Child does not hear well†	1 (0.2%)	1 (0.2%)	1.03 (0.06-16.44)	1.00
Child does not talk like other toddlers his/her age†	25 (6.0%)	30 (7.0%)	0.86 (0.51-1.43)	.58
Cannot understand most of what child says†	10 (2.4%)	18 (4.2%)	0.57 (0.27-1.23)	.18
Child does not walk, run, or climb like other toddlers her/his age†	12 (2.9%)	5 (1.2%)	2.48 (0.88-6.96)	.09
Child has had medical problems in the past several months†	86 (20.8%)	63 (14.8%)	1.41 (1.05-1.89)	.02
Something about child is worrying†	40 (9.7%)	47 (11.0%)	0.88 (0.59-1.31)	.57

* There were 40 children in the planned cesarean birth group and 29 children in the planned vaginal birth group for whom the ASQ was not done and who had a neurodevelopmental assessment only.

† There were a few missing responses for these variables; medical problems included upper respiratory, gastrointestinal, ear, skin, allergies, and other problems.

‡ For each category (communication, gross motor, fine motor, problem solving, and personal-social), the respondent indicated whether the child could do 6 separate activities or tasks by ticking either "yes," "sometimes," or "not yet"; "yes" was scored as 10, "sometimes" was scored as 5, and "not yet" was scored as 0; the maximum score for each category was 60.

§ For communication, a score of <36.5 at 24 months or <38.8 at 30 months was considered abnormal.

‖ For gross motor, a score of <36.0 at 24 months or <30.6 at 30 months was considered abnormal.

¶ For fine motor, a score of <36.4 at 24 months or <25.2 at 30 months was considered abnormal.

For problem-solving skills, a score of <32.9 at 24 months or <28.9 at 30 months was considered abnormal; for personal-social skills, a score of <35.6 at 24 months or <36.9 at 30 months was considered abnormal.

terms of outcomes of children at 2 years of age. Planned cesarean birth did not reduce the risk of death or neurodevelopmental delay at 2 years of age, compared with planned vaginal birth. This is in contrast to our earlier report that found a marked reduction in the risk of perinatal or neonatal death or serious neonatal morbidity with a policy of planned cesarean birth.[6] Why would planned cesarean birth have an important effect on early neonatal outcomes but not on later outcomes in childhood?

Given that the follow-up rate was high (almost 80%) among the selected centers that agreed to undertake this part of the study, we do not believe that the lack of an effect was due to selection bias, despite small differences in some baseline characteristics between groups. Also, the types of morbidity that were experienced by the 18 children with serious neonatal morbidity who were followed to 2 years of age did not appear to be less severe than those that were experienced by the original cohort of 53 children with serious neonatal morbidity in the Term Breech Trial.

One reason for the lack of effect may have been that our study was underpowered. With a sample size of 920 children, we had 80% power of finding only a very large

Table III Death or neurodevelopmental delay, excluding Down syndrome

Final Assessment	Planned cesarean birth (n = 457)	Planned vaginal birth (n = 463)	Relative risk (95% CI)	*P* value
Median age of child (mo; 5th, 95th percentile) at final assessment*	24.4 (23.0, 32.6)	24.3 (23.0, 30.9)		
Death or neurodevelopmental delay (n)†	14 (3.1%)	13 (2.8%)	1.09 (0.52-2.30)	.85
Low perinatal mortality rate (n/N)‡	12/263 (4.6)	10/259 (3.9)		
High perinatal mortality rate (n/N)	2/194 (1.0)	3/204 (1.5)		
Death before 28 days of age (n)§	1	5		
Death after 28 days of age (n)‖	1	1		
Neurodevelopmental delay (n)¶	12	7		

* Excludes deaths.

† Risk difference (95% CI) = +0.3% (−1.9%, +2.4%): countries with low perinatal mortality rates had a national perinatal mortality rate of ≤20 per 1000 births; countries with high perinatal mortality rates had a national perinatal mortality rate of >20 per 1000 births.[8]

‡ *P* value for interaction = .66.

§ These deaths were reported previously as part of the primary outcome of the main trial.[6]

‖ One child in the planned cesarean birth group died after cardiac surgery; 1 child in the planned vaginal birth group died of complications after surgery for subglottic stenosis, which was thought to be congenital in origin.

¶ Eight of 12 children in the planned cesarean birth group and 4 of 7 children in the planned vaginal birth group had a suspect neurologic examination or a 3-month developmental delay because of global delay (1 child), gross motor delay (1 child), speech delay (3 children), nystagmus because of albinism (1 child) and not specified (2 children) in the planned cesarean birth group, and speech delay (3 children) and not specified (1 child) in the planned vaginal birth group; the other 7 children had an abnormal neurologic examination or gross developmental delay, because of mental retardation (1 child), cerebral palsy (1 child), and speech delay (2 children) in the planned cesarean birth group, and global delay (1 child), speech delay (1 child) and not specified (1 child) in the planned vaginal birth group.

(2.8%-0.3% or lower) reduction in the risk of death or neurodevelopmental delay with planned cesarean birth, compared with planned vaginal birth, and would have needed a sample size of >4000 children to find a reduction in risk from 2.8% to 1.5%.[9]

Also, although there is good evidence for an association between measures of early neonatal morbidity and later death or adverse neurodevelopmental outcome among term or near term infants, the predictive value is low. In the Collaborative Perinatal Project of the National Institute of Neurological and Communicative Disorders and Stroke, liveborn infants of birth weights ≥2501 g had a risk of death in the first year of life of 15.5% and a risk of cerebral palsy of 4.7% if the Apgar score was <4 at 5 minutes, compared with a risk of 1.0% and 0.2% for death and cerebral palsy, respectively, if the Apgar score at 5 minutes was 7 to 10.[10] However, if the Apgar score was <4 at 5 minutes but subsequently increased to >4, the risk of death in the first year of life was only 7.7% and the risk of cerebral palsy among survivors was only 0.9%.[10] Thus, most of the children with early neonatal morbidity survived and developed normally.

Also, if a policy of planned cesarean birth for breech presentation at term is to have a beneficial effect on the long-term outcome of children, it is likely only through an ability to reduce the risk of perinatal asphyxia and/or trauma. The risk of cerebral palsy that is due to perinatal asphyxia is exceedingly low, probably approximately 1 in every 1000 births, which increases to approximately 1% to 7% if the Apgar score is <4 at 5 minutes.[10-12] In retrospect, the Term Breech Trial had far too small a sample size to be able to assess the effect of planned cesarean birth on abnormal outcomes of children at 2 years of age.

In summary, compared with planned vaginal birth, planned cesarean birth for the singleton fetus in breech presentation at term is not associated with a reduction in the risk of death or neurodevelopmental delay at 2 years of age. This is because most children with serious neonatal morbidity survive and develop normally. However, planned cesarean birth does reduce perinatal or neonatal mortality rates and serious neonatal morbidity rates in the first 6 weeks of life.

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Appendix

Term Breech Trial Collaborative Group for 2-Year Follow-up of Children

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