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Is planned vaginal delivery for breech presentation at term still an option? Results of an observational prospective survey in France and Belgium

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ABSTRACT

Objective: A large trial published in 2000 concluded that planned vaginal delivery of term breech births is associated with high neonatal risks. Because the obstetric practices in that study differed from those in countries where planned vaginal delivery is still common, we conducted an observational prospective study to describe neonatal outcome according to the planned mode of delivery for term breech births in 2 such countries.
Study design: Observational prospective study with an intent-to-treat analysis to compare the groups for which cesarean and vaginal deliveries were planned. Associations between the outcome and planned mode of delivery were controlled for confounding by multivariate analysis. The main outcome measure was a variable that combined fetal and neonatal mortality and severe neonatal morbidity. The study population consisted of 8105 pregnant women delivering singleton fetuses in breech presentation at term in 138 French and 36 Belgian maternity units.
Results: Cesarean delivery was planned for 5579 women (68.8%) and vaginal delivery for 2526 (31.2%). Of the women with planned vaginal deliveries, 1796 delivered vaginally (71.0%). The rate of the combined neonatal outcome measure was low in the overall population (1.59%; 95% CI [1.33-1.89]) and in the planned vaginal delivery group (1.60%; 95% CI [1.14-2.17]). It did not differ significantly between the planned vaginal and cesarean delivery groups (unadjusted odds ratio = 1.10, 95% CI [0.75-1.61]), even after controlling for confounding variables (adjusted odds ratio = 1.40, 95% CI [0.89-2.23]).
Conclusion: In places where planned vaginal delivery is a common practice and when strict criteria are met before and during labor, planned vaginal delivery of singleton fetuses in breech presentation at term remains a safe option that can be offered to women.

Keywords: Breech presentation Mode of delivery Neonatal morbidity Observational survey

Vaginal deliveries for breech presentations have long been a topic of debate.[1] The Term Breech Trial by Hannah et al, published in 2000, confirmed for many physicians that neonatal risks associated with term breech births are much higher among planned vaginal deliveries and implied that cesarean deliveries should be systematically planned for all such women.[2,3]

Vaginal delivery of breech infants remains standard practice in France. In 1998, the proportion of planned vaginal deliveries among term breech infants here was 51.2%, and 65.1% of this group actually delivered vaginally.[4] In 2000, the French College of Gynecologists and Obstetricians (CNGOF) defined the optimal criteria for deciding to attempt vaginal delivery (Table I).[5,6] Although the internal validity of Hannah's trial is irrefutable, some aspects raise questions about the extrapolation of its results to other settings. The absolute risk of mortality and serious perinatal morbidity for the planned vaginal birth group in countries with low perinatal mortality rates was high (5.7%), as was the difference between the 2 groups (14 times higher in the vaginal than in the systematic cesarean delivery group). These risks were higher than reported in recent European series.[7-11] Moreover, its obstetric practices appear to differ from those in countries where planned vaginal delivery is still offered to a large proportion of women with term breech presentations and satisfied only in part French guidelines for planned vaginal delivery. For example, pelvimetry was performed for only a minority of women. Management of labor for planned vaginal births also differed from French practices, with major disparities in methods of fetal surveillance, criteria for optimal dilatation rate, and duration of active pushing.[12]

Because our objective was to describe neonatal morbidity and mortality for term breech births for the entire population and according to the planned mode of delivery in countries where vaginal delivery is standard practice, we decided to conduct an observational survey without modifying obstetric practices.

METHODS

Patients and study design

Prospective data collection in maternity units volunteering for the PREMODA (PREsentation et MODe d'Accouchement: presentation and mode of delivery) study took place from June 1, 2001, through May 31, 2002, in 138 centers in France, for 232,999 births, and from January 1, 2002, through December 31, 2002, in 36 centers in Belgium, for 31,106 births. The study was approved by the National Commission for Data Protection in Paris on May 9, 2001. It included all women giving birth in a participating maternity unit to a singleton fetus in breech presentation at term (≥37 weeks' gestation), alive or not. The study did not modify patient management. A local investigator in each center was responsible for prospective data collection and monitoring data quality. This person forwarded data regularly to the regional and then national coordination offices, which also monitored them prospectively. Finally, at the end of the study, the national coordinator (M.C.) visited 20 randomly selected centers to evaluate data collection. Detailed reports were obtained (and supplemental information requested if necessary) for all deaths before discharge and transfers to neonatal intensive or intermediate care units. All existing autopsy reports were sought and obtained. All congenital anomalies and reasons for hospitalization were coded according to the 10th edition of the International Classification of Diseases.[13] All deaths before discharge—fetal, neonatal, and postneonatal deaths—were reviewed by an independent expert committee (members listed in Appendix) to determine the cause of each death and whether a planned cesarean delivery at 39 weeks (as recommended by the CNGOF) might have prevented it.

Outcomes and factors studied

The principal outcome measure was a composite variable, similar to that used in the Term Breech Trial[2] and including fetal and neonatal mortality and serious morbidity. It was defined as fetal or neonatal mortality at less than 28 days of age before discharge (excluding lethal congenital anomalies) or 1 or more of the following: birth trauma, including subdural hematoma, intracerebral or intraventricular hemorrhage, spinal-cord injury, basal skull fracture, peripheral-nerve injury present at discharge, or clinically significant genital injury; seizures occurring at less than 24 hours of age; 5-minute Apgar score of less than 4, intubation and ventilation for at least 24 hours, tube feeding for at least 4 days, or admission to the neonatal intensive care unit for longer than 4 days.

We examined the case files and recorded the items recommended by the CNGOF as a basis for deciding mode of delivery and the elements used for managing and monitoring labor (Table I). All participating centers systematically used continuous electronic fetal heart rate monitoring for fetal surveillance.

Table I- *Items recommended by the CNGOF as a basis for deciding mode of delivery (2000 CNGOF guidelines [www.cngof. asso.fr]) and the elements used for describing management and monitoring labor*

Items recommended by the CNGOF as a basis for deciding mode of delivery
Normal pelvimetry
No hyperextension of fetal head (checked with ultrasonography)
Fetal weight estimated between 2500 and 3800 g (with clinical and ultrasound examinations)
Frank breech
Continuous electronic fetal heart-rate monitoring for fetal surveillance during labor
Patient's informed consent
Elements used for describing management and monitoring labor
Induction or augmentation of labor with intravenous oxytocin
Lack of progress
Duration of the first stage of labor
Duration of passive and active phases of the second stage
Station at beginning of active pushing
Methods of vaginal breech delivery (spontaneous, assisted systematically, assisted for difficulty in delivery, manual or instrumental extraction)

Sample size

We calculated that at least 4640 women had to be enrolled for us to be able to show a significant doubling of neonatal risk in the planned vaginal delivery group compared with the planned cesarean group (2% vs 1%; type II error = 0.20, 2-sided type I error of 0.05), with a planned cesarean rate of 50% for the entire population.

Definition of the study groups

Our objective was to compare neonatal status according to the antenatal decision about mode of delivery. The planned cesarean delivery group was made up of the cesarean deliveries before labor, those planned before but performed after labor began and the vaginal deliveries when a cesarean delivery had been planned. All other women were considered to belong to the planned vaginal delivery group.

Table II- *Maternal and obstetric characteristics in the planned vaginal and planned cesarean delivery groups*

	Planned vaginal delivery N = 2,526 n (%)	Planned caesarean section N = 5,579 n (%)	*P*
Maternal age			
≤21 y	164 (6.6)	287 (5.2)	.02
22-34 y	1941 (77.9)	4301 (77.8)	
≥35 y	387 (15.5)	939 (17.0)	
Geographic origin			
French	1802 (72.0)	3756 (67.9)	<.001
Belgian	147 (5.9)	638 (11.5)	
European	112 (4.5)	253 (4.6)	
North African	185 (7.4)	339 (6.1)	
Subsaharan African	64 (2.6)	127 (2.3)	
Other	88 (3.5)	172 (3.1)	
Unspecified	102 (4.1)	249 (4.5)	
Educational level			
Primary school or less	98 (3.9)	179 (3.2)	.005
Middle school	461 (18.3)	898 (16.1)	
Secondary school	357 (14.1)	916 (16.4)	
Postsecondary	851 (33.7)	1825 (32.7)	
Not specified	759 (30.1)	1761 (31.6)	
Parity			
Nullipara	1187 (47.2)	3249 (58.7)	<.001
Primipara	754 (30.0)	1487 (26.8)	
> 1 para	573 (22.8)	805 (14.5)	
Uterine scar			
No	2451 (98.1)	4620 (83.4)	<.001
Single Scar	45 (1.8)	742 (13.4)	
Two or more scars	3 (0.1)	175 (3.2)	
Type of breech:			
Complete breech	750 (29.7)	1530 (27.4)	<.001
Frank breech	1669 (66.1)	3052 (54.7)	
Unspecified	107 (4.2)	997 (17.9)	
Size of the maternity ward (births per y)			
<1000	239 (9.5)	682 (12.2)	<.001
≥1000 and <2000	1093 (43.3)	2450 (43.9)	
≥2000	1194 (47.2)	2447 (43.9)	
Type of the maternity ward			
Public	2035 (80.6)	1227 (22.0)	.009
Private	491 (19.4)	4352 (78.0)	

Analysis

We first described the mode of delivery, cesarean indications and all fetal and neonatal deaths according to cause of death and mode of delivery. Obstetric practices related to the criteria for mode of delivery and the methods for monitoring labor were examined for the entire population, and the 2 groups compared for the neonatal morbidity criteria. Finally, all the factors associated with the principal outcome measure with a *P* value less than .10 were included in a logistic regression model to obtain an adjusted odds ratio for planned vaginal delivery.

The groups were compared with a χ^2 test (or exact Fisher test if required) for the analysis of categorical variables, and a 2-sided *P* value of less than .05 was defined as a significant difference. Statistical comparisons and logistic regressions were performed with Stata software version 8 (Stata Corp, College Station, TX).

Table III- *Mode of delivery, birth weight, gestational age, and performance of a pelvimetry in the planned vaginal and planned cesarean delivery groups*

	Planned vaginal delivery N = 2526 n (%)	Planned cesarean section N = 5579 n (%)	*P*
Mode of delivery			
Cesarean before labor	0	4791 (85.8)	<.001
Cesarean during labor	732 (29.0)	757 (13.6)	
Vaginal delivery	1794 (71.0)	31 (0.6)	
Reasons for cesarean before labor			
Breech	0	2083 (43.5)	
Fetopelvic disproportion	0	906 (18.9)	
Uterine scar	0	535 (11.2)	
Patient's request	0	468 (9.8)	
Fetal condition	0	182 (3.8)	
Maternal associated disease	0	174 (3.6)	
Other reasons	0	359 (7.5)	
Unspecified	0	84 (1.7)	
Reasons for cesarean during labor			
Planned cesarean section	0	757	
Failure to progress	185 (25.3)	0	
FHR anomalies	101 (13.8)	0	
Failure to progress and FHR anomalies	77 (10.5)	0	
Diverse other reasons	332 (45.3)	0	
Unspecified	37 (5.1)	0	
Gestational age			
37 wks	289 (11.5)	668 (12.0)	<.001
38 wks	497 (19.7)	2094 (37.6)	
39 wks	715 (28.3)	1984 (35.6)	
40 wks	688 (27.3)	559 (10.0)	
≥41 wks	336 (13.3)	267 (4.8)	
Birth weight			
<2500 g	154 (6.1)	293 (5.3)	<.001
≥2500 and <3000 g	758 (30.1)	1604 (28.8)	
≥3000 and <3500 g	1104 (43.7)	2351 (42.1)	
≥3500 and <4000 g	443 (17.6)	1090 (19.6)	
≥4000 g	63 (2.5)	235 (4.2)	
Birth weight for gestational age*			
<10th	142 (5.7)	228 (4.1)	<.001
≥10th and ≤ 90th	2142 (86.2)	4610 (83.3)	
>goth	202 (8.1)	700 (12.6)	
Pelvimetry performed	2064 (82.5)	3044 (55.5)	<.001

* Birth weight for gestational age was defined by birth weight <l0th, 10th-90th, and >90th percentile of the birth weight distribution curve of Lubchenco et al.[25]

RESULTS

During the 12-month study period, 1,133 women were included in Belgium and 6,972 in France, for a total of 8,105 women delivering singleton fetuses in breech presentation at term. During the inclusion period, 264,105 births took place in the 174 centers, for a rate of singleton term fetuses in breech presentation of 3.1% (8,105/264,105). Tables II and III report the general maternal and obstetric characteristics for the planned vaginal and cesarean delivery groups. The rate of planned cesarean delivery for the entire sample was 68.8% (n = 5,579) and differed widely between centers (median [10th-90th percentile] = 69.8% [47.8%-89.0%]). Breech presentation was the only reason for 43.5% of the cesarean deliveries before labor (n = 2,083). The rate of cesarean delivery during labor for the entire sample was 18.4% (n = 1,489), nearly half because women for whom cesarean delivery was planned went into labor before the date planned (n = 757, 50.7%). In all, 1,825 women (22.5%) gave birth vaginally.

Table IV- *Fetal and neonatal mortality and morbidity (excluding lethal congenital anomalies) in the planned vaginal delivery and planned caesarean section groups*

	Planned vaginal delivery N = 2502 n (% 95% CI)	Planned caesarean section N = 5573 n (% 95% CI)	OR [95% CI]
5-min Apgar			
<4*	4 (0.16 [0.04-0.41])	1 (0.02 [0.00-0.10])	8.92 [1.00-79.8]
<7	37 (1.48 [1.04-2.03])	26 (0.46 [0.30-0.68])	3.20 [1.93-5.30]
Total injuries	45 (1.80 [1.31-2.40])	26 (0.46 [0.30-0.68])	3.90 [2.40-6.34]
Fracture clavicle	15	5	
Fracture of humerus	2	0	
Other fractures	0	4	
Brachial plexus injuries*	5	4	
Parietal skull fracture*	1	0	
Sternocleidomastoid injury	3	0	
Cutaneous wound with suture	1	4	
Hematoma, contusions	13	5	
Other injuries	5	4	
Transfer to NICU	54 (2.16 [1.63-2.81])	91 (1.63 [1.32-2.00])	1.33 [0.94-1.86]
NICU >4 days*	23 (0.92 [0.58-1.38])	53 (0.95 [0.71-1.24])	0.97 [0.59-1.58]
Intubation	26 (1.04 [0.68-1.52])	32 (0.57 [0.39-0.81])	1.82 [1.08-3.06]
Persistent after the first 24 h*	10 (0.40 [0.19-0.73])	21 (0.38 [0.23-0.58])	1.06 [0.50-2.26]
Transfer to NICU	140 (5.60 [4.73-6.57])	280 (5.04 [4.47-5.68])	1.12 [0.91-1.38]
Convulsions	4 (0.16 [0.04-0.41])	7 (0.13 [0.05-0.26])	1.27 [0.37-4.33]
Continued after first 24 h*	1 (0.04 [0.00-0.22])	4 (0.07 [0.02-0.18])	0.56 [0.06-4.98]
Parenteral or tubal feeding >4 days*	15 (0.60 [0.34-0.98])	32 (0.57 [0.39-0.81])	1.04 [0.56-1.93]
IVH	1 (0.04 [0.00-0.22])	2 (0.04 [0.004-0.13])	1.11 [0.10-12.28]
Grade 1	0	1	
Grade 2	1	1	
Fetal death*	2 (0,08 [0.009-0.28])	7 (0,13 [0.05-0.26])	0.64 [0.13-3.06]
Neonatal death*	0	1 (0.02 [0.00-0.10])	—
Fetal and neonatal mortality or serious neonatal morbidity	40 (1.60 [1.14-2.17])	81 (1.45 [1.16-1.81])	1.10 [0.75-1.61]

Frequencies of morbidity criteria are calculated for live births. Intention-to-treat analysis of morbidity according to the planned mode of delivery includes 8075 subjects rather than 8105 (difference = 30) because this analysis excludes the 17 neonatal deaths with lethal malformations (6 planned vaginal delivery and 11 planned cesarean sections), the 4 in utero deaths with lethal malformations (all vaginal delivery), the pregnancy termination because of severe congenital CMV infection (vaginal delivery) and the 8 in utero deaths without a decision about mode of delivery (all vaginal delivery) (17 + 4+ 1 + 8 = 30). *NICU,* Neonatal intensive care unit; *IVH,* intracerebral ventricular hemorrhage; *CMV,* cytomegalovirus.

* Criteria included in the combined outcome "Fetal and neonatal mortality or serious neonatal morbidity."

The combined stillbirth and neonatal mortality rate was 3.9 per thousand births (22 fetal deaths and 10 neonatal deaths). In all, 6 of the 22 fetal deaths, and 17 of the 18 neonatal or postneonatal deaths before discharge were associated with a lethal congenital anomaly. Two of these deaths occurred in the delivery room, one associated with severe pontocerebellar atrophy and the other with severe ichthyosis. The only neonatal death not associated with a lethal congenital anomaly was sudden and unexplained, at home on day 15, and no cause was found.

Seven fetal deaths occurred at or after 39 weeks. The independent expert committee considered that 3 could have been avoided if the woman had received adequate antenatal care and agreed to a planned cesarean delivery at 39 weeks. In the first case, a woman who had already 2 previous caesarean deliveries refused 1 here, despite the recommendation of the obstetric team: when she came to the maternity ward at a term of 39 weeks + 3 days for uterine contractions, in utero fetal death was diagnosed and remained unexplained. The second case involved a woman, gravida 2, para 1, with a previous cesarean delivery and normal prenatal care. Trial of vaginal delivery was planned but uterine rupture at 40 weeks resulted in an emergency caesarean delivery; the infant was stillborn. In the third case, the mother (gravida 7, para 5, and 42 years of age) sought prenatal care only during the second half of pregnancy, term was uncertain, and the file included no decision about mode of delivery. When she arrived at the maternity ward in labor at a term of 39 weeks + 6 days, fetal death was diagnosed and remained unexplained.

Fetal or neonatal death or serious neonatal morbidity without lethal congenital anomalies was reported for 129 infants, or 1.59% of the entire sample (95% CI [1.33-1.89]) and for 40 infants in the planned vaginal delivery group (1.60% 95% CI [1.14-2.17]). Table IV shows the perinatal outcome according to planned mode of delivery, after excluding lethal congenital anomalies. The groups did not differ significantly for the combined outcome of fetal or neonatal mortality or serious morbidity (odds ratio [OR] = 1.10, 95% CI [0.75-1.61]. Of the criteria included in this combined variable, only a 5-minute Apgar score less than 4 was significantly more frequent in the planned vaginal group (n = 4 vs n = 1, OR = 8.9, 95% CI [1.00-79.8]). Of the other individual outcomes, the following were significantly more frequent in the planned vaginal than in the planned cesarean group: 5-minute Apgar score less than 7 (OR = 3.2, 95% CI [1.9-5.3]), total injuries (OR = 3.9, 95% CI [2.4-6.3]), and intubation (OR = 1.8, 95% CI [1.08-3.1]).

Factors significantly associated with fetal or neonatal mortality or severe morbidity with a threshold less than 0.10 were maternal age, educational level, parity, gestational age at delivery, birth weight, performance of pelvimetry, status of the maternity ward, and cesarean delivery before labor for fetal condition. After controlling for risk factors, the risk of fetal or neonatal mortality or serious morbidity was not significantly different among the planned vaginal and cesarean groups (adjusted OR = 1.40 95%CI [0.89-2.23]).

Table V reports management during labor and delivery for the vaginal deliveries.

Comment

This prospective study showed a global risk of 1.59% (95% CI [1,33-1,89]) for fetal or neonatal mortality or serious neonatal morbidity among the overall population of singleton term breech infants. Vaginal delivery for breech presentation at term remained a common practice in 2001 through 2002 in France and Belgium (22.5%). Under the standard practice conditions, neonatal outcome was not significantly poorer among infants with planned vaginal than with planned cesarean deliveries.

The participating maternity units account for a substantial portion of the births in France (29.3%) (232,999/ 796,000) and French-speaking Belgium (47.9%) (31,106/ 65,000). Inclusion of all term breech infants in each unit during the study period ensures that results represent current practices in these units. We included an average of 60 women per center during the study year and systematically recorded all available information about antenatal decisions as well as neonatal mortality and morbidity. The methodology we used allows us to meet the primary objectives of PREMODA, to describe practices on a daily basis for the entire population, and to assess neonatal mortality and morbidity in breech presentations in countries where vaginal delivery is still widely practiced.

***Table V-** Management of Labor and delivery for vaginal deliveries*

	N = 1,825, N (%)
Induction of labor	163 (8.9)
First method used for induction:	
Prostaglandins	45 (28.7)
Oxytocin	111 (70.7)
Mechanical means	1 (0.6)
Oxytocin augmentation without labor induction	1107 (74.1)
Lack of progress in dilatation	
None	1534 (87.2)
At least 1 failure to progress > 1 h	144 (8.2)
At least 1 failure to progress > 2 h	67 (3.8)
At least 2 episodes of failure to progress >l h	14 (0.8)
Duration of first stage of labor between 5 and 10 cm dilatation	
<4 h	1208 (66.2)
4-6 h	248 (13.6)
≥7 h	25 (1.4)
Unspecified	344 (18.8)
Duration of passive phase of second stage of labor	
<30 min	1,093 (63.9)
30-60 min	308 (18.0)
≥60 min	310 (18.1)
Duration of active phase of second stage of labor	
<30 min	1671 (94.0)
30-60 min	103 (5.8)
≥60 min	4 (0.2)
Station at beginning of active pushing	
High	63 (3.6)
Mid	507 (28.5)
Low	1,017 (57.1)
Unspecified	195 (10.8)
Maneuvers during delivery	
None	633 (35.3)
Systematic*	543 (30.3)
For extended arms	226 (12.6)
For entrapped fetal head	71 (4.1)
For extended arms and entrapped fetal head	109 (6.1)
Other	151 (8.4)
Maneuvers and forceps for entrapped fetal head	57 (3.2)
Difficulties during expulsion	87 (4.8)
Senior obstetrician present at delivery	1657 (92.3)

* Many teams have a set of maneuvers they use routinely for breech deliveries, even when no difficulties arise.

Most large studies of term breech deliveries are retrospective and based on registry data. They generally report considerably increased neonatal risks in the vaginal delivery group.[1,14-16] The many patients included in such studies allow statistically significant comparisons but their results are difficult to interpret because of the questionable validity and sparseness of the antenatal and postnatal information. In the PRE-MODA study, data were collected to answer the question about the association between mode of delivery and serious neonatal morbidity or mortality. Thus, we meticulously examined causes of death and morbidity. We noted neonatal conditions, including genetic syndromes and metabolic diseases, which were diagnosed days, or even weeks after birth, and required specific research. Of the 129 cases of fetal or neonatal death or severe neonatal morbidity, 33 (25.6%) had nonlethal major or minor malformations that sometimes explained the abnormal neonatal condition. Similarly, large retrospective studies cannot deal with the question of prelabor decisions about mode of delivery because information about this decision was not collected. Prospective data recording

enables an "intention-to-treat" analysis according to planned mode of delivery.

Although the groups were compared by an intention-to-treat analysis, their comparability cannot be guaranteed, as in a randomized controlled trial, and the multivariate analysis cannot completely control for all the confounding factors. Nonetheless, any selection bias is limited here by adjustment for factors such as educational level, quality of antenatal care, existence of a preliminary decision about mode of delivery, indications for the planned cesarean, and especially for fetal disorders.

Several examinations are performed routinely ante-natally to help decide mode of delivery. Although evidence-based proof of their usefulness is not available, the high rate of their performance is indicative of special attention to the decision. For example, comparison of PREMODA and the Term Breech Trial shows that physicians in the former used pelvimetry in the planned vaginal delivery group much more often (82.4% vs 9.8%).[2] Management of labor also differed between these studies. Fetal surveillance of all PREMODA cases, but only 33.4% of those in the Term Breech Trial, used continuous FHR. The percentage of women with an active phase of the second stage of labor longer than 60 minutes was only 0.2% versus 5.0% in the Term Breech Trial.[17,18] A secondary analysis of the latter reported that an adverse perinatal outcome was associated with an active phase of the second stage 60 minutes or more.[17] Active pushing began after the presenting part reached the high pelvic straits in only 3.6% of cases (information not reported in the Term Breech Trial). French guidelines recommend waiting to initiate active pushing in breech presentation until the presenting part reaches the outlet. This practice often leads to a long passive phase of the second stage of labor: 60 minutes or more in 18.1% in the PREMODA study versus 3.1% in the Term Breech Trial.[17] Finally, only 3.8% of cases in our vaginal delivery group involved labor that failed to progress for more than 2 hours.

The PREMODA results in the planned vaginal delivery group can be extrapolated only to centers where planned vaginal deliveries are still relatively common. In a retrospective, population-based cohort study of 100,667 breech deliveries in California, Gilbert et al reported a high neonatal death rate among nullipara women in vaginal breech deliveries (OR 9.2, 95% CI [3.3,25.6]), but no information about antenatal care or labor. The paucity of vaginal deliveries (2.5%), however, indicates that this subgroup is probably quite particular.[14]

Similarly, the PREMODA results can be extrapolated only to centers that apply strict criteria before and during labor. The low risk in the planned vaginal delivery group may be associated with more prudent obstetric practices since the publication of the Term Breech Trial. According, the rate of cesarean delivery before labor for singleton term breech infants in France has increased from 49.0% in 1998 to 75.0% in 2003 (Enquête National Périnatale 2003, unpublished data), a rise also seen in the Netherlands, Australia, and New Zealand.[4,19,20] Although we do not have historic data for neonatal outcome in France, it is possible that the situation is similar to that observed in the Netherlands, where perinatal mortality decreased from 0.35% to 0.18% between 1998 and 2002.[21]

The fetal or neonatal mortality or serious neonatal morbidity in planned vaginal deliveries in our study was barely one quarter that reported in the Term Breech Trial in its subgroup covering countries with low national perinatal mortality rates (1.6% vs 5.7%). Although some individual unfavorable outcomes in the planned vaginal delivery group were similar between the 2 studies (intubation for more than 24 hours, trauma), most occurred more frequently in the Term Breech Trial (Apgar <4, seizures, brachial plexus injuries, intraventricular hemorrhage, neonatal deaths, excluding lethal malformations). Neither study, however, had enough subjects to interpret these individual outcomes meaningfully, this is why a combined outcome was necessary.

We did not find the excess risk associated with planned vaginal delivery that the Term Breech Trial observed for the subgroup covering countries with low national perinatal mortality rates (relative risk [RR] = 14.3, CI 95% [3.4-50.0]).[2] Moreover, their recent subgroup analysis found that the prevalence of death or abnormal neurodevelopment at 2 years did not differ according to study group (vaginal or cesarean).[22] When we consider only deaths rather than morbidity, our study included only 1 neonatal death of a nonmalformed newborn infant and that 1 was in the planned cesarean group.

Except for a 5-minute Apgar score less than 4 (n = 4 vs n = 1, respectively), none of the severe individual outcomes differed significantly between groups. The composite outcome was selected because it was very similar to that used in the Term Birth Trial and because the PREMODA scientific study considered it to be a thorough characterization of a poor condition in term neonates likely to result in long-term sequelae. Some other individual neonatal outcomes were significantly higher in the planned vaginal than in the cesarean delivery group. Among these individual outcomes, some cases, probably those at highest risk, were included in the composite variable because they met more serious criteria (ie, 16/63 of those with an Apgar score < 7; 40/58 of

intubated infants; 13/71 of those with trauma). The multivariate analysis was based only on the principal outcome variable, precisely to avoid multiple comparisons that increase the risk of observing significant differences by chance, especially in small groups.

We are not the only group to have obtained results along this line: numerous recent studies that applied a relatively widespread policy of planned vaginal delivery, in various practice conditions, did not observe this excess risk.[7-11] The methodology for studying policies for managing delivery of term breech infants necessarily differs somewhat from that for studying the biologic effect of drugs. Randomized trials assessing a management policy are necessary but difficult to extrapolate to other practice conditions.[23,24] It is accordingly essential to assess a management policy in a population under conditions of everyday practice.

CONCLUSION

In centers where planned vaginal delivery remains a widespread practice and in complying with rigorous conditions before and during labor, we did not find a significant excess risk associated with planned vaginal delivery compared with planned cesarean for women with a singleton fetus in breech presentation at term. There may be a slightly higher neonatal risk associated with planned vaginal delivery but it is very different from that reported in the only published large randomized trial. Under the conditions discussed here, planned vaginal delivery of singleton fetuses in breech presentation at term remains a safe clinical option that can be offered to women after providing them with clear, objective, and complete information.

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APPENDIX

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All members of the Writing, Scientific, and the Data Monitoring and Analysis committee have seen and approved the final version of the manuscript.

The study was approved by the National Commission for Data Protection in Paris (on 9 May, 2001).