Articles

Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial

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Summary

Background For 3–4% of pregnancies, the fetus will be in the breech presentation at term. For most of these women, the approach to delivery is controversial. We did a randomised trial to compare a policy of planned caesarean section with a policy of planned vaginal birth for selected breech-presentation pregnancies.

Methods At 121 centres in 26 countries, 2088 women with a singleton fetus in a frank or complete breech presentation were randomly assigned planned caesarean section or planned vaginal birth. Women having a vaginal breech delivery had an experienced clinician at the birth. Mothers and infants were followed-up to 6 weeks post partum. The primary outcomes were perinatal mortality, neonatal mortality, or serious neonatal morbidity; and maternal mortality or serious maternal morbidity. Analysis was by intention to treat.

Findings Data were received for 2083 women. Of the 1041 women assigned planned caesarean section, 941 (90·4%) were delivered by caesarean section. Of the 1042 women assigned planned vaginal birth, 591 (56·7%) delivered vaginally. Perinatal mortality, neonatal mortality, or serious neonatal morbidity was significantly lower for the planned caesarean section group than for the planned vaginal birth group (17 of 1039 [1·6%] *vs* 52 of 1039 [5·0%]; relative risk 0·33 [95% CI 0·19–0·56]; p<0·0001). There were no differences between groups in terms of maternal mortality or serious maternal morbidity (41 of 1041 [3·9%] *vs* 33 of 1042 [3·2%]; 1·24 [0·79–1·95]; p=0·35).

Interpretation Planned caesarean section is better than planned vaginal birth for the term fetus in the breech presentation; serious maternal complications are similar between the groups.

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Introduction

About 3–4% of all pregnancies reach term with a fetus in the breech presentation.[1] Data from previously published cohort studies have shown that, in general, planned caesarean section is better than planned vaginal birth for the fetus that presents as a breech at term.[2,3] These studies are potentially biased, however, because women were not allocated to the different modes of delivery at random. Other concerns are that the studies might have included pregnancies that would not currently be considered for a trial of labour (eg, footling breech presentation [with the feet entering the birth canal ahead of any other part of the body]), and that clinicians undertaking vaginal breech deliveries may not have been experienced in the technique. Two randomised controlled trials and a Cochrane meta-analysis of these trials have not found planned caesarean section to be associated with substantial benefits for the fetus, but both trials had very small sample sizes.[4–6]

There is a general consensus that planned caesarean section is better than planned vaginal birth for the delivery of the fetus in the breech presentation at term if the presentation is footling, if the fetus is compromised, if the fetus is large or has a congenital abnormality that could cause a mechanical problem at vaginal delivery, or if a clinician experienced in vaginal breech delivery is not available.[7] However, for most breech fetuses at term, the best approach by which to deliver is controversial. Some clinicians believe a policy of planned caesarean section is best because of the results of observational studies, whereas others remain sceptical since there is no evidence from randomised controlled trials that perinatal outcome is improved with a policy of planned caesarean section. We undertook the Term Breech Trial to determine whether planned caesarean section was better than planned vaginal birth for selected fetuses in the breech presentation at term. The study was done in centres that could assure women having a vaginal breech delivery that an experienced clinician would be present at the birth.

Methods

Patients

Women were eligible for the trial if they had a singleton live fetus in a frank or complete breech presentation at term (≥37 weeks' gestation). Frank breech presentation was defined as hips flexed, knees extended; complete breech was defined as hips flexed, knees flexed, but feet not below the fetal buttocks. Women were excluded if there was evidence of fetopelvic disproportion, if the fetus was judged to be clinically large or to have an estimated fetal weight of 4000 g or more, if there was hyperextension of the fetal head, if the clinician judged

there to be a fetal anomaly or condition that might cause a mechanical problem at delivery (such as hydrocephalus), or if there was a contraindication to either labour or vaginal delivery (such as placenta praevia). These eligibility criteria were agreed at a pretrial consensus meeting.[7] Women were also excluded if there was a known lethal fetal congenital anomaly.

The study was approved by the research ethics committees at all participating centres, and women gave informed consent before enrolling in the study.

Methods

Randomisation was centrally controlled at the University of Toronto Maternal Infant and Reproductive Health Research Unit with a computerised randomisation program, accessible by means of a touch-tone telephone. Randomisation was stratified by parity (0 and ≥1) with block sizes of two. We did not stratify by centre, since we would have had to use large block sizes to avoid unmasking of allocation, and large block sizes could have resulted in imbalance since we expected that some centres would enrol only a few women.

Women who were eligible for the study and consented to participate were randomly allocated to either the planned caesarean section or the planned vaginal birth group. If assigned to the planned caesarean section group, a caesarean section was scheduled for 38 or more weeks' gestation. If the gestational age of the fetus was in doubt, the caesarean was undertaken after confirming the maturity of the fetus or by waiting for spontaneous labour. If the woman was in labour at the time of randomisation, the caesarean section was undertaken as soon as possible. Immediately before caesarean section, the fetal presentation was reassessed and if cephalic, a vaginal birth was planned. We expected that more than 90% of women in the planned caesarean section group would deliver by caesarean section.

If randomised to the planned vaginal birth group, management was expectant until spontaneous labour began, unless an indication to induce labour (eg, post-term pregnancy) or to undertake a caesarean section (eg, footling breech presentation) developed. The protocol for management during labour, which was agreed at the pretrial consensus meeting,[7] was as follows: induction of labour and amniotomy were allowed for standard obstetrical indications; the fetal heart rate was monitored either intermittently (every 15 min in the first stage and every 5 min in the second stage of labour), or continuously, by means of electronic fetal heart-rate monitoring; augmentation of labour with intravenous oxytocin was regarded as reasonable to treat ineffective uterine contractions, so long as the clinician was confident that there was no evidence of fetopelvic disproportion; adequate labour progress in the first stage of labour was defined as a rate of cervical dilation of at least 0·5 cm/h after the onset of active labour, and in the second stage, as descent of the breech to the pelvic floor within 2 h of full dilatation, with delivery being imminent within 1 h of beginning active pushing; if fetal heart-rate abnormalities or lack of progress in labour occurred, a caesarean section was undertaken; otherwise, labour was allowed to progress and the baby was delivered vaginally; the choice of analgesia and anaesthesia was left to the woman and her care providers; the method of delivery was by assisted or spontaneous breech delivery with control of the aftercoming head—the important elements being no intervention until there was spontaneous exit of the infant to the umbilicus and minimum intervention thereafter with no traction on the body, and controlled delivery of the aftercoming head usually either with the use of forceps or the Mauriceau-Smellie-Veit manoeuvre; clinicians used their judgment in the choice of these manoeuvres; total breech extraction was not permitted. We expected that more than 50% of women in the planned vaginal birth group would deliver vaginally.

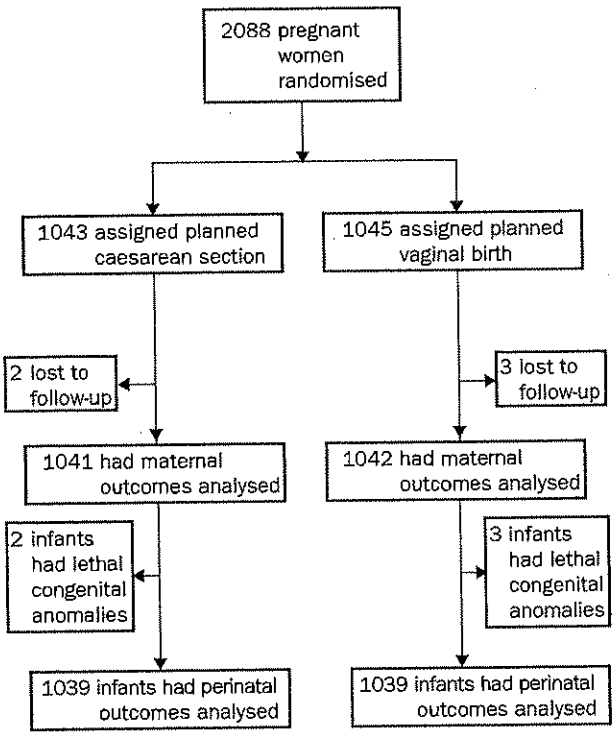
Babies in the breech presentation who were delivered vaginally were attended by an experienced clinician—ie, someone who considered himself or herself to be skilled and experienced at vaginal breech delivery, with confirmation by the individual's head of department (hereafter referred to as the a-priori definition). Before beginning recruitment in each centre, we assigned clinicians who were regarded as experienced at vaginal breech delivery a code number, and recorded information on their qualifications and years of experience of vaginal breech delivery. Similar information was collected if other clinicians were present at delivery. Cord blood was taken for assessment of pH and base deficit. Women having caesarean section received intraoperative antibiotics. Otherwise the care of mothers and babies was according to standard practice in the participating centres.

We monitored compliance with the study protocol regularly for all participants in terms of mode of delivery, and for those having a vaginal breech birth, to determine that an experienced clinician was present at delivery, that labour was not prolonged (duration of first stage of labour <18 h, time from full dilatation to active pushing <2 h, and time from active pushing to delivery <1·5 h), that the breech presentation at delivery was either frank or complete, and to check that total breech extraction was not done.

Mothers were followed-up until 6 weeks post partum, whenever possible, to determine the occurrence of complications for either mother or baby after discharge from hospital. A 3-month and 2-year follow-up of mothers and babies is continuing in selected centres.

The primary outcome was perinatal or neonatal mortality at less than 28 days of age (excluding lethal congenital anomalies), or one or more of the following measures of serious neonatal morbidity: birth trauma, which included subdural haematoma, intracerebral or intraventricular haemorrhage, spinal-cord injury, basal skull fracture, peripheral-nerve injury present at discharge from hospital, or clinically significant genital injury; seizures occurring at less than 24 h of age or requiring two or more drugs to control them; Apgar score of less than 4 at 5 min; cord-blood base deficit of at least 15; hypotonia for a least 2 h; stupor, decreased response to pain, or coma; intubation and ventilation for at least 24 h; tube feeding for 4 days or more; or admission to the neonatal intensive care unit for longer than 4 days. These definitions of serious neonatal morbidity were identified previously by experts as important measures of term or post-term neonatal morbidity.[8] All reported outcomes were checked with the centres to ensure accuracy.

The secondary outcome was maternal mortality or serious maternal morbidity during the first 6 weeks post partum, which included one or more of the following: death; postpartum haemorrhage of more than 1500 mL or need for blood transfusion; dilatation and curettage for bleeding or retained placental tissue; hysterectomy; cervical laceration involving the lower uterine segment (in



Trial profile

Characteristic	Planned caesarean section (n=1041)	Planned vaginal birth (n=1042)
Maternal age (years)		
≥30	339 (32·6%)	331 (31·8%)
<30	702 (67·4%)	711 (68·2%)
Parity		
0	547 (52·6%)	545 (52·3%)
1–4	434 (41·7%)	434 (41·7%)
>4	60 (5·8%)	63 (6·1%)
Type of breech presentation		
Frank	655 (62·9%)	637 (61·1%)
Complete	340 (32·7%)	362 (34·7%)
Uncertain	46 (4·4%)	43 (4·1%)
Gestational age ≥41 weeks	67 (6·4%)	65 (6·2%)
In labour	434 (41·7%)	456 (43·8%)
Membranes ruptured	253 (24·3%)	233 (22·4%)
Estimated fetal size or weight*		
Average size or ≥3000 g	689 (66·2%)	680 (65·3%)
Small size and <3000 g	352 (33·8%)	362 (34·7%)
Method of estimating fetal size or weight		
Clinical only	418 (40·2%)	427 (41·0%)
Ultrasonography†	623 (59·9%)	615 (59·0%)
Method of assessing adequacy of pelvis		
Clinical only	950 (91·3%)	940 (90·2%)
Radiography, MRI, or CT†	91 (8·7%)	102 (9·8%)
Method of assessing attitude of fetal head		
Clinical only	319 (30·6%)	326 (31·3%)
Ultrasonography or radiography†	722 (69·4%)	716 (68·7%)
Previous attempt at external cephalic version	228 (21·9%)	220 (21·1%)
National perinatal mortality rate		
Low (≤20/1000)	515 (49·5%)	512 (49·1%)
High (>20/1000)	526 (50·5%)	530 (50·9%)
Standard of care in centre‡		
High	366 (35·2%)	369 (35·4%)
Usual	674 (64·8%)	673 (64·6%)

MRI=magnetic resonance imaging; CT=computed tomography. *If the clinical and ultrasonography estimates of fetal size differed (eg, the estimated size of the fetus clinically was small but by ultrasonography ≥3000 g or the estimated size of the fetus clinically was average but by ultrasonography <3000 g), the fetus was regarded as average size or ≥3000 g. †With or without clinical method. ‡There was one missing value for the caesarean group.

Table 1: **Baseline characteristics**

the case of a vaginal delivery); vertical uterine incision or serious extension to a transverse uterine incision (in the case of caesarean section); vulvar or perineal haematoma requiring evacuation; deep-vein thrombophlebitis or pulmonary embolism requiring anticoagulant therapy; pneumonia; adult respiratory-distress syndrome; wound infection requiring prolonged hospital stay, as an inpatient or outpatient, or readmission to hospital; wound dehiscence or breakdown; maternal fever of at least 38·5°C on two occasions at least 24 h apart, not including the first 24 h; bladder, ureter, or bowel injury requiring repair; genital-tract fistula; bowel obstruction; or other serious maternal morbidity. All other outcomes of maternal morbidity were judged by members of the steering committee, masked to allocation group and if possible to mode of delivery, to determine whether they might be related to the delivery and whether they should be regarded as serious.

We undertook multiple logistic-regression analyses to test for interactions between baseline characteristics and treatment group for the major outcomes. For the combined outcome of perinatal mortality, neonatal mortality, or serious neonatal morbidity, for the outcome of perinatal or neonatal mortality, and for the outcome of serious neonatal morbidity, we tested for interactions between treatment group and the baseline characteristics of maternal age (≥30 *vs* <30 years); parity (0 *vs* 1–4 *vs* >4); type of breech presentation (frank *vs* complete or uncertain); gestational age (≥41 weeks *vs* <41 weeks); labour (*vs* no labour); ruptured (*vs* intact) membranes; estimated fetal size or weight (clinically average fetal size or ≥3000 g on ultrasonography *vs* clinically small fetal size and <3000 g on ultrasonography); method of assessing fetal size or weight (clinical only *vs* ultrasonography [with or without clinical]); method of assessing adequacy of pelvis (clinical only *vs* radiography, magnetic resonance imaging, or computerised tomography [with or without clinical]); method of assessing attitude of fetal head (clinical only *vs* ultrasonography or radiography [with or without clinical]); previous attempt at external cephalic version (yes *vs* no); standard of care provided in the centre (high *vs* usual) based on responses to a survey administered during the study; the country's perinatal mortality rate as reported in 1996 by WHO (low [≤20/1000] *vs* high [>20/1000]),[9] and by the total number of women recruited in the centre (≤20 *vs* >20). Centres classified as providing care at a high standard had: the ability to undertake a caesarean section within 10 min, if necessary (*vs* 10–60 min), of making the decision to do so; someone usually available in the delivery room to resuscitate a depressed baby, by giving oxygen by bag and mask immediately (*vs* within 10 min) or by endotracheal intubation and positive-pressure ventilation immediately (*vs* within 30 min); and personnel and facilities on-site to resuscitate and ventilate a baby requiring ventilation for more than 24 h (*vs* needing to transfer the baby to another hospital). Countries with a low perinatal mortality rate were Australia, Canada, Chile, Denmark, Finland, Germany, Israel, Netherlands, New Zealand, Poland, Portugal, Romania, Switzerland, UK, USA, and Yugoslavia.[9] Countries with a high perinatal mortality rate were Argentina, Brazil, Egypt, India, Jordan, Mexico, Pakistan, Palestine, South Africa, and Zimbabwe.[9]

Event	Planned caesarean section (n=1041)	Planned vaginal birth (n=1042)	p
Presentation at delivery*			0·02
Breech	1018 (97·8%)	994 (95·5%)	
Cephalic†	19 (1·8%)	39 (3·7%)	
Oblique/transverse lie	4 (0·4%)	8 (0·8%)	
Mode of delivery			<0·0001
Caesarean section before labour	470 (45·2%)	75 (7·2%)	
Caesarean section after labour	471 (45·2%)	376 (36·1%)	
Vaginal delivery	100 (9·6%)	591 (56·7%)	
General anaesthesia	294 (28·2%)	132 (12·7%)	<0·0001
Epidural or spinal analgesia/anaesthesia	682 (65·5%)	482 (46·3%)	<0·0001
Abruptio placenta	0	6 (0·6%)	0·03
Cord prolapse	0	14 (1·3%)	0·0001
Before labour	0	2 (0·2%)	
During labour	0	12 (1·2%)	
Clinical chorioamnionitis‡	3 (0·3%)	11 (1·1%)	0·06
Fetal heart-rate abnormalities*	13 (1·3%)	156 (15·2%)	<0·0001
Difficulty with delivery of fetal head, arms, shoulder, or body	22 (2·1%)	48 (4·6%)	0·002
Time from randomisation to delivery ≥7 days*	156 (15·0%)	301 (28·9%)	<0·0001
Median (5th–95th centile) gestational age at delivery (weeks)*	39·3 (37·5–41·2)	39·6 (37·5–41·8)	<0·0001
Time in hospital before delivery ≥48 h*	74 (7·1%)	91 (8·8%)	0·19

*For these variables there were a few missing values. †The difference in cephalic births between groups was significant (p=0·02). ‡Defined as a temperature >38°C before delivery.

Table 2: **Characteristics of labour and delivery**

For the outcome of maternal mortality or serious maternal morbidity, we tested for interactions between treatment group and the baseline characteristics of maternal age (≥30 *vs* <30 years), parity (0 *vs* 1–4 *vs* >4), labour (*vs* no labour), ruptured (*vs* intact) membranes, standard of care provided in the centre (high *vs* usual), and by the country's reported perinatal mortality rate (low *vs* high).

We explored the effects of planned caesarean section versus planned vaginal birth if an experienced clinician was confirmed to be present at vaginal breech delivery by comparing the rates of the combined outcome of perinatal mortality, neonatal mortality, or serious neonatal morbidity in the two randomised groups, excluding cases of vaginal breech delivery that were undertaken without an experienced individual. For these analyses, we defined a skilled and experienced clinician in four ways: (1) according to our a-priori definition; (2) as simply a licensed obstetrician; (3) as a clinician with more than 10 years of experience of vaginal breech delivery; and (4) as a clinician with more than 20 years of experience of vaginal breech delivery.

We also explored the effects of planned caesarean section versus planned vaginal birth after exclusion of vaginal breech deliveries that followed prolonged labour, after labour was induced or augmented with oxytocin or prostaglandins, if there was a footling or uncertain type of breech presentation at delivery, or if the vaginal breech delivery was undertaken without a skilled and experienced clinician present at the birth (according to our a-priori definition). Lastly, we repeated this analysis after excluding women having a vaginal breech delivery without an epidural anaesthetic.

Statistical analysis

The required sample size was calculated to be 2800. This sample size had 80% power to find a reduction in risk of perinatal or neonatal mortality or serious neonatal morbidity from 0·8% with planned vaginal birth to 0·1% with planned caesarean section (one-sided type I error of 0·05). One interim analysis was planned for when complete data had been received on the first 1000 women randomised, with the aim of stopping the study if a difference was found between groups at p<0·002 (two-sided). An independent data monitoring committee reviewed the data for this interim analysis and recommended a second interim analysis after data had been received on the first 1600 women randomised. After reviewing the results of the second interim analysis, the data monitoring committee recommended that recruitment be stopped, since the difference in the rate of the primary outcome between groups was significant at p<0·002. Recruitment was stopped the following day on April 21, 2000. While obtaining complete data for the first 1600 women randomised, an additional 488 women

Characteristic	Planned caesarean section (n=88)	Planned vaginal birth (n=558)
Induced labour	4 (4·6%)	83 (14·9%)
Induced labour with oxytocin or prostaglandins	3 (3·4%)	82 (14·7%)
Augmented labour	24 (27·3%)	278 (49·8%)
Augmented labour with oxytocin or prostaglandins	21 (23·9%)	266 (47·7%)
Epidural analgesia	23 (26·1%)	140 (25·1%)
Prolonged labour*	6 (6·8%)	20 (3·6%)
First stage ≥18 h	2 (2·3%)	1 (0·2%)
Second stage (no pushing) ≥2 h	1 (1·1%)	4 (0·7%)
Second stage (pushing) ≥1·5 h	3 (3·4%)	15 (2·7%)
Presentation at delivery		
Frank	55 (62·5%)	371 (66·5%)
Complete	29 (33·0%)	179 (32·1%)
Footling or uncertain	4 (4·5%)	8 (1·4%)
Type of vaginal delivery		
Spontaneous or assisted without forceps	67 (76·1%)	435 (78·0%)
Assisted with forceps	21 (23·9%)	123 (22·0%)
Experienced clinician at delivery*	82 (93·2%)	543 (97·3%)
Licensed obstetrician at delivery*	71 (80·7%)	436 (78·4%)
Clinician at delivery with >10 years vaginal breech-delivery experience*	50 (56·8%)	332 (60·0%)
Clinician at delivery with >20 years vaginal breech-delivery experience*	18 (20·5%)	133 (24·1%)

*For these variables there were a few missing values.

Table 3: **Characteristics of labour and delivery for women who had a vaginal breech delivery**

were randomised to the study. Thus the total number randomised was 2088.

The results were analysed according to intention to treat, and all women who underwent randomisation and for whom data were available were included in the analysis. Lethal congenital anomalies were excluded from the analysis of perinatal and neonatal outcomes. Perinatal and neonatal deaths were excluded from the analysis of neonatal morbidity. Maternal death was excluded from the analysis of maternal morbidity. The groups were compared by means of Fisher's exact test for the analysis of categorical variables, and Wilcoxon's rank-sum test for the analysis of continuous variables that were not normally distributed. A one-sided p value of less than 0·05 was regarded as indicative of significance for differences in rates of perinatal mortality, neonatal mortality, or serious neonatal morbidity, and a two-sided p value of less than 0·05 indicated significance for differences in rates of maternal mortality or serious maternal morbidity. Relative risks and 95% CI were reported for differences in the major outcomes. The additional number of caesarean sections needed to avoid one baby with a primary outcome was calculated by dividing the difference in the rates of caesarean section in the two groups by the difference in the rates of the primary outcome. The p values reported for other outcomes should be regarded as descriptive; no adjustments were made for multiple tests.

Results

We enrolled 2088 women between Jan 9, 1997, and April 21, 2000, at 121 centres in 26 countries. We received entry and outcome data for 2083 (99·8%) women, of whom 1041 were randomised to the planned caesarean section group and 1042 to the planned vaginal birth group (figure). Baseline characteristics were similar in both groups (table 1). 1027 (49·3%) women were from centres with a low perinatal mortality rate, and 1056 (50·7%) were from centres with a high perinatal mortality rate. The numbers of women recruited in each centre are available from the authors.

For women randomised to the planned caesarean section group, 941 (90·4%) were delivered by caesarean section. For the 100 women delivered vaginally in the planned caesarean section group, the reasons were: caesarean not possible due to imminent vaginal delivery (59), patient's request (29), cephalic presentation (12), and other or unknown reasons (five). For those randomised to the planned vaginal birth group, 591 (56·7%) were delivered vaginally. For the 451 delivered by caesarean section in that group, the reasons were: fetopelvic disproportion or failure to progress in labour (226 [50·1%]), fetal heart-rate abnormality (129 [28·6%]), footling breech presentation (69 [15·3%]), patient's request (61 [13·5%]), obstetrical or medical complication (45 [10·0%]), cord prolapse (12 [2·7%]), or other or unknown reason (eight [1·8%]). Labour and delivery events for all women are detailed by randomised group in table 2. For the 646 women who had a vaginal breech delivery, compliance with the protocol was excellent (table 3). Overall, only 58 (9·0%) of these women had a prolonged labour, a footling or uncertain type of breech presentation at delivery, or did not have a skilled and experienced clinician at the birth, according to our a-priori definition (table 3). No infants were delivered by total breech extraction.

	Allocated delivery method	Actual delivery method	Other information
1	Vaginal birth	Caesarean section	P=0; FHR abnormalities; difficult attempt at vaginal delivery before caesarean section; BW=3370 g; ND
2	Vaginal birth	Vaginal birth	P=1; intrauterine death of a twin, probably before enrolment; BW=1150 g
3	Vaginal birth	Vaginal birth	P=0; fetal heart tones disappeared during second stage of labour too late to undertake caesarean section; BW=2965 g; SB
4	Vaginal birth	Vaginal birth	P=0; difficult vaginal delivery; BW=2400 g; SB
5	Caesarean section	Vaginal birth	P=0; difficult vaginal delivery; BW=2550 g; SB
6	Vaginal birth	Vaginal birth	P=0; baby discharged home well; died during sleep; BW=2000 g
7	Vaginal birth	Vaginal birth*	P=6; difficult vaginal delivery; baby had a small head, low set ears and deep set eyes; BW=3500 g; ND
8	Vaginal birth	Vaginal birth	P=0; difficult vaginal delivery; BW=3000 g; SB
9	Vaginal birth	Vaginal birth*	P=0; baby discharged home well; died after developing severe vomiting and diarrhoea; BW 2500 g
10	Vaginal birth	Vaginal birth	P=1; FHR abnormalities; fetal heart tones disappeared before a caesarean section could be started; BW=2700 g; SB
11	Caesarean section	Caesarean section	P=3; respiratory problems after prelabour caesarean section; 2300 g; ND
12	Vaginal birth	Vaginal birth*	P=2; respiratory problems; BW=2500 g; ND
13	Vaginal birth	Vaginal birth	P=0; respiratory problems; BW=2700 g; ND
14	Vaginal birth	Vaginal birth	P=0; difficult vaginal delivery; BW=3050 g; SB
15	Vaginal birth	Vaginal birth	P=4; intrauterine death, of cephalic presentation; probably before enrolment BW=3650 g
16	Caesarean section	Caesarean section	P=0; FHR abnormalities; ruptured myelomeningocele; BW=2850 g; ND

FHR=fetal heart rate. P=parity; SB=stillbirth; ND=neonatal death; BW=birthweight; cases 1–3 were from countries with a low national perinatal mortality rate; cases 1, 3, 5, 8, and 15 were delivered at 41 or more weeks' gestation; cases 1–4, 6–9, and 15 had labour induced or augmented with oxytocin or prostaglandins; only case 1 had an epidural anaesthetic; no cases had prolonged labour; for cases 1–14 an experienced clinician was present; cases 1–5, 7–9, 12, 13, and 16 were in frank breech presentation; cases 6, 10, and 14 were in complete breech presentation; case 11 was an uncertain type of breech presentation. *Vaginal birth with forceps to aftercoming head.

Table 4: **Details of stillbirths and neonatal deaths (excluding lethal anomalies)**

Five babies had lethal congenital anomalies (anencephaly [one], dysmorphic syndrome with multiple cardiac anomalies [one], trisomy 18 [one], and cyanotic congenital heart disease [two]) and were excluded from the analyses of all perinatal and neonatal outcomes. 16 other babies died, and these were excluded from the analyses of the outcomes of neonatal morbidity. Details of the stillbirths and neonatal deaths are given in table 4 (the full details can be found on *The Lancet*'s website [www.thelancet.com]. Six of the 16 deaths were associated with difficult vaginal delivery, and four were associated with fetal heart-rate abnormalities in labour. There was a significantly lower risk of the combined outcome of perinatal or neonatal mortality or of serious neonatal morbidity in the planned caesarean section group than in the planned vaginal birth group (table 5),

Outcome	Planned caesarean section	Planned vaginal birth	Relative risk (95% CI)	p
Perinatal/neonatal mortality or serious neonatal morbidity*	17/1039 (1·6%)	52/1039 (5·0%)	0·33 (0·19–0·56)	<0·0001
Low national PMR	2/514 (0·4%)	29/511 (5·7%)		
High national PMR	15/525 (2·9%)	23/528 (4·4%)		
Perinatal/neonatal mortality†	3/1039 (0·3%)	13/1039 (1·3%)	0·23 (0·07–0·81)	0·01
Low national PMR	0/514	3/511 (0·6%)		
High national PMR	3/525 (0·6%)	10/528 (1·9%)		
Serious neonatal morbidity‡	14/1036 (1·4%)	39/1026 (3·8%)	0·36 (0·19–0·65)	0·0003
Low national PMR	2/514 (0·4%)	26/508 (5·1%)		
High national PMR	12/522 (2·3%)	13/518 (2·5%)		

PMR=perinatal mortality rate. *p=0·005 for interaction between treatment and national PMR for combined outcome of perinatal/neonatal mortality or serious neonatal morbidity. †p=0·96 for interaction between treatment and national PMR for outcome of perinatal/neonatal mortality. ‡p=0·003 for interaction between treatment and national PMR for outcome of serious neonatal morbidity.

Table 5: **Perinatal or neonatal mortality at <28 days of age and serious neonatal morbidity**

and there was also a significantly lower risk of perinatal or neonatal mortality in the planned caesarean section group than in the planned vaginal birth group (table 5). The difference in rates of perinatal or neonatal mortality remained significant (p=0·03) when the analysis was repeated excluding the two babies that had probably died before enrolment. There was a significantly lower risk of serious neonatal morbidity in the planned caesarean section group than in the planned vaginal birth group (table 5). The individual measures of neonatal morbidity are detailed in table 6.

There were no significant differences in maternal mortality or serious morbidity between the planned caesarean section and planned vaginal birth groups (table 7). There was one maternal death in the planned vaginal birth group. The mother was jaundiced before labour, developed disseminated intravascular coagulation after vaginal delivery, and died from hepatorenal failure at 44 h post partum.

For the combined outcome of perinatal mortality, neonatal mortality, or serious neonatal morbidity, and for the outcomes of perinatal or neonatal mortality, and of serious neonatal morbidity, there were no significant interactions between treatment group and maternal age, parity, type of breech presentation, gestational age, presence of labour, presence of ruptured membranes, estimated size or weight of fetus, method of assessing fetal size or weight, method of assessing adequacy of pelvis, method of assessing attitude of fetal head, previous attempt at external cephalic version, standard of care provided by the centre, or total number of women recruited in the centre.

However, there was a significant interaction between treatment group and the country's reported perinatal mortality rate for the combined outcome of perinatal mortality, neonatal mortality, or serious neonatal morbidity (p=0·005). Since the cut-off points of ⩽20/1000 and >20/1000 were somewhat arbitrarily chosen, we also confirmed that use of the cut-off points ⩽10/1000 and >10/1000, and of ⩽15/1000 and >15/1000 did not change the significance of the interaction. The reduction in risk from planned caesarean section compared with planned vaginal birth was much greater in countries with a low perinatal mortality rate (2/514 [0·4%] *vs* 29/511 [5·7%]; 0·07 [0·02–0·29]; p<0·0001), than in countries with a high perinatal mortality rate (15/525 [2·9%] *vs* 23/528 [4·4%]; 0·66 [0·35–1·24]; p=0·13). This finding occurred despite larger differences in rates of caesarean section between the planned caesarean section and planned vaginal birth groups for countries with a high perinatal mortality rate (90·7% *vs* 31·7%) than for countries with a low perinatal mortality rate (90·1% *vs* 55·3%). There was no significant interaction between treatment group and the country's reported perinatal mortality rate for the outcome of perinatal or neonatal mortality (p=0·96). There was a significant interaction between treatment group and the country's reported perinatal mortality rate for the outcome of serious neonatal morbidity (p=0·003), with the reduction in risk from planned caesarean section compared with planned vaginal birth being much greater in countries with a low perinatal mortality rate (2/514 [0·4 %] *vs* 26/508 [5·1%]; 0·08 [0·02–0·32]; p<0·0001), than in countries with a high perinatal mortality rate (12/522 [2·3%] *vs* 13/518 [2·5%]; 0·92 [0·42–1·99]; p=0·49).

For the outcome of maternal mortality or serious morbidity, there were no significant interactions between treatment group and maternal age, parity, labour, ruptured membranes, standard of care provided by the centre, or the country's reported perinatal mortality rate.

	Planned caesarean section	Planned vaginal delivery	p
Birth trauma	6 (0·6%)	14 (1·4%)	0·05
Intracerebral or intraventricular haemorrhage*	0	2 (0·2%)	
Spinal-cord injury*	1 (0·1%)	0	
Basal skull fracture*	1 (0·1%)	0	
Fracture of long bone or clavicle	1 (0·1%)	6 (0·6%)	
Brachial plexus injury*†	2 (0·2%)	5 (0·5%	
Significant genital injury*	1 (0·1%)	2 (0·2%)	
Seizures	1 (0·1%)	7 (0·7%)	0·03
During first 24 h*	0	6 (0·6%)	
Needing ⩾2 drugs*	1 (0·1%)	3 (0·3%)	
Hypotonia	2 (0·2%)	18 (1·8%)	0·0002
⩾2 h*	2 (0·2%)	11 (1·1%)	
Abnormal level of consciousness	6 (0·6%)	16 (1·6%)	0·02
Hyperalert, drowsy, or lethargic	6 (0·6%)	13 (1·3%)	
Stupor/decreased response to pain*	0	1 (0·1%)	
Coma*	0	2 (0·2%)	
Apgar <7 at 5 min‡	8 (0·8%)	31 (3·0%)	0·0001
Apgar <4 at 5 min*‡	1 (0·1%)	9 (0·9%)	0·01
Cord-blood base deficit ⩾15*¶	4/453 (0·9%)	13/446 (2·8%)	0·02
Cord-blood pH <7·00¶	2/510 (0·4%)	13/503 (2·6%)	0·003
Intubation and ventilation	3 (0·3%)	13 (1·3%)	0·01
>24 h*	1 (0·1%)	4 (0·4%)	
Tube feeding	12 (1·2%)	32 (3·1%)	0·002
⩾4 days*	2 (0·2%)	6 (0·6%)	
Care in neonatal ICU	16 (1·5%)	31 (3·0%)	0·02
>4 days*	4 (0·4%)	6 (0·6%)	
Birthweight >4000 g‡	32 (3·1%)	59 (5·8%)	0·002
Birthweight <2500 g‡	48 (4·6%)	49 (4·8%)	0·48

ICU=intensive care unit. *Denotes measures of serious neonatal morbidity included in primary outcome (there were no cases of subdural haematoma). †All were present at discharge from hospital and five were improving. ‡There were a few missing values for Apgar score and birthweight. ¶Cord blood (arterial if available, otherwise venous) was not taken for some infants.

Table 6: **Details of neonatal morbidity**

Complication	Planned caesarean section	Planned vaginal birth	Relative risk (95% CI)	p
Maternal mortality or serious morbidity	41/1041 (3·9%)	33/1042 (3·2%)	1·24 (0·79–1·95)	0·35
Maternal mortality	0	1 (0·1%)	..	..
Postpartum bleeding*	10/1041 (1·0%)	13/1041 (1·3%)		0·68
Haemorrhage >1000 mL	4 (0·4%)	8 (0·8%)		
Haemorrhage >1500 mL†	2 (0·2%)	4 (0·4%)		
Requiring blood transfusion†	4 (0·4%)	8 (0·8%)		
Requiring dilatation and curettage†	3 (0·3%)	4 (0·4%)		
Other†‡	2 (0·2%)	1 (0·1%)		
Genital-tract injury§	6/1041 (0·6%)	6/1041 (0·6%)	..	1·0
Vertical uterine incision†	1 (0·1%)	1 (0·1%)		
Serious extension to transverse uterine incision†	5 (0·5%)	3 (0·3%)		
Cervical laceration extending to lower uterine segment†	0	1 (0·1%)		
Vulvar/perineal haematoma requiring evacuation†	0	1 (0·1%)		
Wound infection, dehiscence, or breakdown*	16/1041 (1·5%)	10/1041 (1·0%)	..	0·32
Infection†¶	15 (1·4%)	9 (0·9%)		
Dehiscence or breakdown†	6 (0·6%)	2 (0·2%)		
Maternal systemic infection*	16/1041 (1·5%)	13/1041 (1·3%)	..	0·71
Postpartum fever ≥38·0°C**	16 (1·5%)	13 (1·3%)		
Postpartum fever ≥38·5°C**	13 (1·3%)	10 (1·0%)		
Pneumonia†	1 (0·1%)	0		
Other infection†‡	1 (0·1%)	1 (0·1%)		
Early postpartum depression†‡	3/1041 (0·3%)	0	..	..
Median (5th–95th centile) time in hospital after delivery (days)	4·0 (1·7–7·4)	2·8 (0·8–6·9)	..	<0·0001

*More than one response may apply. †Denotes measure of serious maternal morbidity included in secondary outcome (there were no cases of hysterectomy; genital-tract fistula; adult respiratory-distress syndrome; bowel obstruction; injury to bladder, ureter, or bowel; deep-vein thrombophlebitis; or pulmonary embolism). ‡Other complications judged as serious were: three women with postpartum bleeding (one had bleeding from her uterine incision requiring laparotomy and transfusion of 2000 mL, one had retained placental tissue requiring dilatation and curettage at 3 months, one had a wound haematoma requiring blood transfusions); two women had serious systemic infections (one with splenic abscess, the other with chills and diarrhoea due to clostridium); and three women had early postpartum depression. §There were a few missing values for type and extension of uterine incision. ¶Defined as requiring prolonged hospital stay, as an inpatient or outpatient, or readmission to hospital. **Defined as occurring on two occasions at least 24 h apart, not including the first 24 h.

Table 7: **Maternal mortality and morbidity**

When vaginal breech births without an experienced clinician present at the birth were excluded from the analysis, the risk of the combined outcome of perinatal mortality, neonatal mortality, or serious neonatal morbidity with planned caesarean section, compared with planned vaginal birth was 17/1033 (1·7%) versus 50/1024 (40·9%; 0·34 [0·20–0·58]; p<0·0001) if an experienced clinician was defined as a clinician who judged him or herself to be skilled at vaginal breech delivery, as confirmed by the head of department (the a priori definition); 16/1021 (1·6%) versus 42/913 (4·6%; 0·34 [0·19–0·60]; p<0·0001) if an experienced clinician was defined simply as a licensed obstetrician; 15/992 (1·5%) versus 28/793 (3·5%; 0·43 [0·23–0·80]; p=0·005), if an experienced clinician was defined as one with more than 10 years' vaginal breech-delivery experience; and 15/960 (1·6%) versus 19/595 (3·2%; 0·49 [0·25–0·96]; p=0·03) if an experienced clinician was defined as one with more than 20 years of vaginal breech-delivery experience.

When we excluded from the analysis vaginal breech deliveries that occurred after a prolonged labour, after labour was induced or augmented with oxytocin or prostaglandins, those for which there was a footling or uncertain type of breech presentation at delivery, and those for whom there was no skilled and experienced clinician present at the birth (according to our a-priori definition), the risk of the combined outcome of perinatal mortality, neonatal mortality, or serious neonatal morbidity with planned caesarean section, compared with planned vaginal birth, was 16/1006 (1·6%) versus 23/704 (3·3%; 0·49 [0·26–0·91]; p=0·02). When we repeated this analysis after also excluding women having a vaginal breech delivery without an epidural anaesthetic, the results were similar (14/961 [1·5%] *vs* 15/518 [2·9%]; 0·50 [0·24–1·03]; p=0·05).

Discussion

Some clinicians have recommended a policy of caesarean section for breech presentation at term based on results of non-randomised studies, anecdotal experiences, and medicolegal concerns.[2,3,10,11] Other clinicians who are experienced with vaginal breech delivery have continued to recommend planned vaginal birth for selected women, with the view that vaginal birth would be associated with lower morbidity for the mother, would require fewer health-care resources, and would be less costly.[7,12–14] The Term Breech Trial was undertaken to determine whether there are benefits from planned caesarean section compared with planned vaginal delivery for women who are good candidates for a vaginal breech delivery if a clinician experienced in vaginal breech delivery is present at the birth. We confined the trial to centres that had clinicians experienced in vaginal breech delivery, since we wished to give the option of vaginal breech delivery its best, and perhaps last, chance to be proven a reasonable method of delivery. Despite this allowance, we found that the fetuses of women allocated planned caesarean section were significantly less likely to die or to experience poor outcomes in the immediate neonatal period than the fetuses of women allocated planned vaginal birth. Although some of the deaths in the planned vaginal birth group were related to difficulty with vaginal breech delivery, others were clearly associated with problems during labour. Thus the avoidance of labour and vaginal breech delivery could have contributed to better outcomes with planned caesarean section. Overall, with a policy of planned caesarean section, for every additional 14 caesarean sections done, one baby will avoid death or serious morbidity.

The rate of perinatal or neonatal mortality among randomised patients was lower in countries reported to have a low perinatal mortality rate by WHO (0·3% *vs* 1·2%), as one might expect, and there was no significant interaction between the country's reported perinatal mortality rate and treatment group for the outcome of perinatal or neonatal mortality, indicating that fetuses in all countries were similarly less likely to die if delivered by planned caesarean section than if a vaginal birth was planned. However, the rate of serious neonatal morbidity among randomised patients was not lower in countries reported to have a low versus a high perinatal mortality rate (2·7% *vs* 2·4%), and we found a significant interaction between the country's reported perinatal mortality rate and treatment group for the outcome of serious neonatal morbidity, indicating that fetuses born in countries reported by WHO to have a low perinatal mortality rate were much less likely to have serious neonatal morbidity if delivered by planned

caesarean section than if a vaginal birth was planned compared with those born in a country reported to have a high perinatal mortality rate.

One possible explanation is that the reduced benefit of planned caesarean section in countries with a high perinatal mortality rate is an artefact due to detection bias, in that babies in these countries are less likely to be closely observed by caregivers for evidence of birth trauma, the occurrence of seizures, hypotonia, or an abnormal level of consciousness; that mothers in these countries feel less empowered to report problems to health-care workers if they note them; and that most babies, particularly if delivered vaginally, are discharged home before these problems can be detected by health-care workers. Also, babies in these countries could be more likely to die before some of these measures of morbidity can develop. However, the reduced benefit from a policy of planned caesarean section in countries with a high perinatal mortality rate might also be real, possibly because of higher levels of experience with vaginal breech delivery in those countries. If this is the case, in countries with a high perinatal mortality rate, as many as 39 additional caesarean sections could be needed to avoid one dead or compromised baby, whereas in countries with a low perinatal mortality rate, the number of additional caesarean sections needed could be as low as seven.

The finding of better fetal and neonatal outcomes with a policy of planned caesarean section might be disappointing to many obstetricians who are experienced at vaginal breech delivery and have never personally assisted at a difficult vaginal breech birth resulting in a stillbirth or a neurologically depressed or damaged infant. We therefore explored the data to assess treatment effects after excluding mothers that did not have an experienced clinician at vaginal breech delivery, defining an experienced clinician in four different ways. We repeated the analysis after also excluding vaginal breech births that had prolonged labour, labour that was induced or augmented with oxytocin or prostaglandins, or had a breech presentation at delivery that was either footling or of uncertain type, and lastly after also excluding women having a vaginal breech delivery without an epidural anaesthetic. The results did not change: planned caesarean section remained a substantially better method of delivery for the fetus. Although it is possible that our definitions of vaginal breech-delivery experience were not true measures of experience, and that experience today is less than it was 30 or 40 years ago, the results of the Term Breech Trial provide us with reasonable evidence that a policy of planned vaginal birth is no longer to be encouraged for singleton fetuses in the breech presentation.

Overall, we found a low rate of maternal mortality or serious morbidity. Apart from one woman who died for reasons probably unrelated to the method of delivery, only 3·6% of women in the study experienced serious morbidity, and this was not significantly different between the planned caesarean section and planned vaginal birth groups. Serious risks associated with caesarean section could be fewer than previously described.[4] A randomised controlled trial of planned caesarean section compared with planned vaginal birth for women with HIV-1 infection in pregnancy also found low rates of maternal morbidity.[15]

In summary, we have shown that a policy of planned caesarean section is substantially better for the singleton fetus in the breech presentation at term, with the benefits being greater in countries that are reported to have lower perinatal mortality rates. A policy of planned caesarean section is not associated with a higher risk of serious problems for the mother in the first 6 weeks post partum.

Contributors

Mary E Hannah designed the study protocol, supervised the study, and wrote the paper. Walter J Hannah organised the original consensus meeting to develop the selection criteria and intrapartum management protocol for vaginal breech delivery, and responded to protocol queries relating to vaginal breech delivery during the study. Andrew Willan supervised the statistical analyses, which were carried out by Binu Lamba Dhindsa. Sheila Hewson and Julie Weston took responsibility for the day-to-day contacts with the centres and the management of the data. Ellen Hodnett contributed to the analysis and interpretation of maternal outcome data. Saroj Saigal contributed to the analysis and interpretation of neonatal outcome data.

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