

Evolving Evidence Since the Term Breech Trial: Canadian Response, European Dissent, and Potential Solutions

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Abstract

Objectives: We wished to gain insight into Canadian hospital policy changes between 2000 and 2007 in response to (1) the initial results of the Term Breech Trial suggesting delivery by Caesarean section was preferable for term breech presentation, and (2) the trial's two-year follow-up and other research and commentary suggesting that risks associated with vaginal breech delivery and delivery by Caesarean section were similar. We also wished to determine the availability of vaginal breech delivery and the feasibility of establishing breech clinics and on-call squads, and whether these could include midwives.

Methods: In 2006, we sent surveys to the 30 largest maternity centres in Canada asking about their changes in practice in response to results of the initial Term Breech Trial and the subsequent two-year follow-up and the possibility of establishing breech clinics and on-call delivery squads and whether they could include midwives.

Results: Of the 30 surveys sent, responses were received from 20 maternity centres in six provinces. Hospitals were almost five times more likely to adopt a policy of requiring Caesarean section for breech delivery when current evidence suggested that it decreased risk for the neonate than they were to reintroduce the option of vaginal breech delivery when it did not. A breech clinic was considered possible, feasible, and desirable by only one centre, and forming a breech squad was similarly regarded by only two hospitals; 70% of respondents, however, did not entirely dismiss either possibility.

Conclusions: The weight of epidemiologic evidence does not support the practice developed in Canadian hospitals since the Term Breech Trial that recommends delivery by Caesarean section for all breech presentations. Obstetric and midwifery bodies will require creative strategies to make clinical practice consistent with current national and international evidence.

Key Words: Vaginal breech delivery, randomized controlled trials, cohort studies

Competing Interests: None declared.

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Résumé

Objectifs : Nous souhaitions nous familiariser avec les modifications apportées, entre 2000 et 2007, aux politiques au sein des hôpitaux canadiens en réponse (1) aux résultats initiaux du *Term Breech Trial*, lesquels laissaient entendre que l'accouchement par césarienne s'avérait préférable face à une présentation du siège à terme; et (2) au suivi de l'essai pendant deux ans et aux autres recherches et commentaires affirmant que les risques associés à l'accouchement du siège par voie vaginale et ceux qui sont associés à l'accouchement par césarienne étaient semblables. Nous souhaitions également déterminer la disponibilité de l'accouchement du siège par voie vaginale et la faisabilité de la mise sur pied de cliniques et d'équipes sur appel vouées à l'accouchement du siège (nous voulions de plus savoir si ces équipes pouvaient compter des sages-femmes parmi leurs membres).

Méthodes : En 2006, nous avons fait parvenir des sondages aux 30 centres de maternité les plus importants au Canada; ces sondages portaient sur les modifications que ces centres avaient apportées à leurs pratiques en réponse aux résultats initiaux du *Term Breech Trial* et aux résultats du suivi de deux ans subséquent, ainsi que sur la possibilité de mettre sur pied des cliniques et des équipes sur appel vouées à l'accouchement du siège, et d'y inclure des sages-femmes.

Résultats : Vingt des 30 centres de maternité sollicités dans six provinces ont répondu au sondage. Les hôpitaux étaient près de cinq fois plus susceptibles d'adopter une politique exigeant la tenue d'une césarienne en présence d'un accouchement du siège, lorsque les données contemporaines laissaient entendre qu'une telle pratique entraînait une baisse du risque couru par le nouveau-né, que de réintroduire l'option de l'accouchement du siège par voie vaginale, en l'absence de telles données. La mise sur pied d'une clinique vouée à l'accouchement du siège n'a été considérée possible, faisable et souhaitable que par un seul centre; celle d'une équipe vouée à l'accouchement du siège n'a été considérée possible, faisable et souhaitable que par deux hôpitaux. Toutefois, 70 % des répondants n'ont pas entièrement mis de côté l'une ou l'autre de ces possibilités.

Conclusions : Le poids des données épidémiologiques ne soutient pas la pratique, préconisée au sein des hôpitaux canadiens depuis le *Term Breech Trial*, qui recommande la tenue d'un accouchement par césarienne pour toutes les présentations du siège. Les organismes voués à l'obstétrique et à la pratique des sages-femmes devront élaborer des stratégies novatrices pour faire en sorte d'harmoniser les pratiques cliniques avec les données nationales et internationales actuelles.

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INTRODUCTION

In the initial report of the Term Breech Trial, the authors concluded that planned Caesarean section “is better than planned vaginal birth for the term fetus in the breech presentation.”¹ In contrast, the conclusion after the two-year follow-up of neonates from the Term Breech Trial was that delivery by planned Caesarean section “is not associated with a reduction in risk of death or neurodevelopmental delay in children at two years of age.”²

Following publication of the original results from the Term Breech Trial, in 2001¹ the Society of Obstetricians and Gynaecologists of Canada publicly stated “the Executive and Council of the SOGC feel it necessary to advise its members, and the public, that the best method of delivering a term frank or complete breech singleton is by planned LSCS.”³ Some obstetricians, however, remained uneasy about this statement and the recommendation arising from the Term Breech Trial because they conflicted with their instincts and experience.

In 2001 Keirse pointed out the difference in perinatal mortality rates following vaginal breech delivery between countries that had high and low perinatal mortality and questioned how babies in the Term Breech Trial were identified as having serious morbidity:

It is remarkable . . . that there were only 14 babies with serious morbidity in the planned cesarean group, whereas 16 babies of that group ended up in a neonatal intensive care unit. In contrast, 20.5% of babies with serious morbidity in the planned vaginal group (8 of 39) never saw an ICU.⁴

Van Roosmalen and Rosendaal queried the significance of the hypotonia included in the serious morbidity category, since it had disappeared after two hours in 7 of the 18 babies in the planned vaginal delivery group, and they asked what the long-term significance of the hypotonia was in the other 11 babies.⁵ Investigators in a number of centres in Europe, including several in Scandinavia, Germany, France, and Belgium, had not joined the Term Breech Trial because of concerns about the methodology or because they were pursuing research in their own centres (Michael Krause, personal communication, March 2006; Susanne Albrechtsen, personal communication, October 2006; François Goffinet, personal communication, October 2006; Frank Louwen, personal communication, April 2008; and Anke Reitter, personal communication, June 2009).

After the publication of the Term Breech Trial two-year follow-up, it became clear that the large discrepancy in serious morbidity outcomes between Caesarean section and vaginal birth immediately after delivery was short term. Although 5.1% of babies allocated to be delivered vaginally had been

flagged at birth with serious short-term morbidity, compared with 0.4% of babies after Caesarean section, this difference in morbidity had disappeared at the time of the two-year follow-up.²

There were still concerns, however, about increased perinatal mortality. In countries with national mortality rates lower than 20/1000 there were three deaths in the 512 intended vaginal deliveries and none in the 515 deliveries allocated to Caesarean section. On closer analysis, one of the deaths in the vaginal delivery group was an “intrauterine death of a twin probably before enrolment,” delivered macerated and weighing only 1150 g. With this death removed from analysis, the mortality rate for vaginal delivery is 2/512, not significantly different from that in the Caesarean section group. Further, for the other two perinatal deaths in the group allocated to vaginal delivery, there were arguably important errors in obstetrical management.⁶

The studies of breech deliveries in Scandinavia^{7,8} and in France and Belgium⁹ corroborate the conclusions of the two-year Term Breech Trial follow-up rather than the published conclusions of the Term Breech Trial in 2000. That is, they did not find any significant advantage to performing Caesarean section for term breech delivery. Based on the weight of evidence, the SOGC 2009 Clinical Practice Guideline on Vaginal Delivery of Breech Presentation included the following conclusions: “[c]areful case selection and labour management in a modern obstetrical setting may achieve a level of safety similar to elective Caesarean section” and “[p]lanned vaginal breech birth is reasonable in selected women with a term singleton fetus.”¹⁰

In 2006, we conducted a survey across Canada to determine the status of breech delivery at major maternity centres.

METHODS

In 2006, we developed a questionnaire for hospitals to report changes they had made to clinical practice after the release of the original Term Breech Trial results in 2000 and since the report from the Term Breech Trial two-year follow-up. The survey also sought opinions about the feasibility, desirability, and possibility of developing specialty clinics for women whose babies were in the breech position and of developing breech squads. The term “breech squad” means an on-call group of physicians and midwives who agree to provide clinical services in a given geographical area for women wanting to deliver their breech babies vaginally. We limited the length of the questionnaire to maximize response. A list of Canadian health care facilities for 2002–2005 was located on the website “Canadian Health Care Facilities.”¹¹ A questionnaire in English was first sent to the head of obstetrics and the nurse manager of 12 major maternity centres in Canada (in seven provinces); the

questionnaire was subsequently translated into French and sent to the remaining Canadian maternity centres that report 3000 or more births annually. Repeat contacts to elicit a response were made on three separate occasions, ending in September 2006.

When the survey was sent to the maternity centres during the second phase, it was adjusted by adding one question: "Has the informed consent in your hospital changed, that is, has the way you discuss breech births been modified since the two-year follow-up came out?" The initial questionnaire asked whether practice had changed, and, because little change had occurred despite the new information from the two-year follow-up, we wished to learn if this was because the discussion had also not changed. This additional question was also sent to the centres that had previously completed the initial survey.

RESULTS

In all, 30 centres were contacted by phone, fax, or email. Responses were received from 20 maternity centres, through 18 heads of obstetrics and three nurse managers in six provinces (Alberta, British Columbia, Manitoba, Nova Scotia, Ontario, and Saskatchewan). One centre declined to participate, and the remaining nine centres did not respond.

Changes in Canadian Hospitals After the Term Breech Trial 2000

1. Was there an increase in Caesarean section rate?

With the publication of the Term Breech Trial in 2000, the number of Caesarean sections performed for breech delivery increased in 95% of the hospitals, "markedly" in 65% of them (Table 1). Only one centre reported that the number of Caesarean sections for breech did not increase at all.

2. Did Caesarean section for breech delivery become a required protocol?

Of the 20 centres, 11 said that it did not become a required protocol to perform Caesarean section for all breech presentations. One centre did not respond to this question but indicated that they had "developed a specific consent form." Of the remaining eight centres that said that it did become established protocol to perform Caesarean section for all breech presentations, three expressed this with qualifiers. In the first, Caesarean section was planned for all primiparous women, but if a multiparous woman was in active labour, she could plan a vaginal delivery; in the second, women were permitted to choose how they wished to deliver, but they were informed about the findings in the Term Breech Trial; and in the third centre, 99.9% of breech deliveries were by Caesarean section, but occasionally physicians would conduct a vaginal delivery if conditions were favourable.

3. What course of action was taken if a woman refused?

Three of the centres that reported delivery by Caesarean section as required protocol commented. The first reported that no women had refused; they provided informed consent. The second reported that few women refused because they provided informed consent, and the third reported that they would support the woman's decision.

Changes After the Term Breech Trial Two-year Follow-up

By two years after the two-year follow-up to the Term Breech Trial was published, with subsequent commentary, one half of the maternity centres surveyed were aware of the report and had considered its implications in their department (Table 2). Only two of these were able to offer a time period during which that discussion had taken place. Another 35% said some staff members were familiar with the report but that the department had not discussed its implications.

Twenty percent of the hospitals surveyed had changed practice after the two-year follow-up, although there was little description of the changes. Fifty-five percent of them had experienced little change in practice and did not intend to change over the following year (Table 3).

One of the 11 heads of obstetrics, who reported that his centre's practice had changed little since the two-year follow-up, with no intention of changing over the following year, qualified his response by stating that although it had become required protocol to perform all breech deliveries by Caesarean section, women could in fact deliver how they wished. However, they were told that the Term Breech trial indicated that delivery by Caesarean section was preferred. This head reported that vaginal breech delivery was still an option, "but no more women are choosing it anyway."

Only five institutions answered the added question in the second phase of the survey about informed choice. Four of them reported that they had not changed their informed consent document.

Developing Clinics Dedicated to Vaginal Breech Delivery

Participants were asked whether they thought it useful to create a clinic specializing in informing women with a breech presentation about their options for delivery. Seventy percent of the centres surveyed were willing to consider the possibility of a breech clinic, but 30% thought that it was not possible, feasible, or desirable (Table 4). Only two of the centres surveyed thought such a clinic was possible, feasible, and desirable. One of these two centres said that the feasibility would depend on space, finances, and willing practitioners. Of the six other centres that reported it was

possible, one noted that it is currently done “informally since we all know who is ‘on the squad.’”

Five of the hospitals surveyed reported that they did not have midwives at their hospital, two of them being in jurisdictions where midwifery had tenuous legal status. Only one centre, in British Columbia, reported it would be completely possible, feasible, and desirable to have midwives involved in the breech clinic. One Ontario centre reported that it would be “feasible” to have senior midwives included in such a clinic. Another suggested that relations between midwives and physicians would need to improve for it to be feasible.

Developing Breech Squads

With respect to having a breech squad, i.e., a group of practitioners who agree to be part of an on-call group in a given geographical area for women wanting to have a vaginal breech delivery, three quarters of the hospitals replied it was possible, feasible, or desirable (Table 4). Just under one half thought it possible, feasible, or desirable to include senior midwives in the breech squad. Among the 11 centres that reported this option as not possible, feasible, or desirable, one explained it was “because we don’t have midwives at the hospital” and another that “the practitioner capable of offering the full range of care would have to be involved.”

DISCUSSION

In its systematic review of planned Caesarean section for breech presentation versus vaginal breech delivery, the Cochrane Review still excludes any study that is not a randomized controlled trial (RCT).¹² Yet substantial questions have arisen about the appropriateness of this methodology for studying breech delivery.^{13–15}

The first lies in the RCT focus on short-term outcomes; pronouncements about safety are made, and, as our survey suggests, protocols become fixed in stone before the long-term effects of modes of delivery can be analyzed. These longer range effects are seen not only in the two-year follow-up of the Term Breech Trial but also in the growing data on long-term effects of Caesarean section.^{16,17}

A second limitation of the RCT is the prohibitive cost of recruiting a large enough sample to report accurately on the rare outcomes of perinatal and maternal mortality rates, which have been rendered insignificant in the Term Breech Trial because of this limitation. Third, difficulties arise in maintaining standard management across the multitude of sites required to create a large enough sample in an RCT to study even the more common short-term outcomes. These difficulties include variable practitioner experience, the requirement for staff to follow rigid RCT protocols with

Table 1. After the 2000 Term Breech Trial publication did the rate of Caesarean section for breech presentation increase?

Response	n (%)
Markedly	13 (65)
Somewhat	6 (30)
Not at all	1 (5)
Total	20 (100)

Table 2. Awareness of the two-year follow-up of the Term Breech Trial

Response	n (%)
Aware of literature and considered its implications	10 (50)
Some staff are familiar with it but it has not been discussed at the departmental level	7 (35)
No clear response	2 (10)
No response	1 (5)

Table 3. Which comment best describes actions you may or may not have taken since October 2004?

Response	n (%)
Changes have been made at our hospital	4 (20)
We have made little or no change but will be making changes in the near future	3 (15)
Little change since the follow-up of the TBT and do not intend to over the next year	11 (55)

which they are unfamiliar, unequal access to or differences in prenatal diagnoses and monitoring, and unequal access to or use of electronic fetal monitoring, Caesarean section, and neonatal resuscitation equipment.¹⁸

These are among the factors that now suggest to many obstetric units, particularly in Europe, that the outcomes of an RCT comparing modes of breech delivery may not be generalizable to their particular situation. Several institutions have taken the course of performing population-based cohort studies in their own institution for quality assurance and for comparison with other institutions. The weight of evidence of the research conducted concurrent with or since the Term Breech Trial suggests insignificant differences between the outcomes of planned Caesarean section and planned vaginal breech delivery for

Table 4. Opinions regarding a breech clinic and breech squad at your hospital

Opinions Regarding	Breech clinic		Breech squad	
	Staffed by obstetricians n (%)	Staffed by obstetricians and senior midwives n (%)	Possible at your centre? n (%)	Include senior midwives n (%)
Response				
It is possible, feasible, and desirable	2 (10)	1 (5)	1 (4.5)	0 (0)
Possible	6 (30)	0 (0)	6 (27)	3 (16)
Feasible	4 (20)	2 (10)	3 (15)	2 (10)
Desirable	2 (10)	0 (0)	6 (23)*	3 (16)
Not possible, feasible, or desirable	6 (30)	11 (55)	7 (32)	11(58)
No answer or not clear		6 (30)		1 (5)
Total hospitals	20 (100)	20 (100)	20 (100)	20 (100)

*One "desirable but not currently feasible"

carefully selected neonates in large maternity institutions in countries with low perinatal mortality.^{7-9,19-25} A notable exception to this conclusion was the experience in the Netherlands of lowered early neonatal morbidity and mortality associated with an increased rate of Caesarean section performed in response to the results of the Term Breech Trial.^{26,27} However, when it was demonstrated that the increased Caesarean section rate had also raised the maternal mortality rate and increased long-term risks (both perinatal deaths and maternal life-threatening risks such as uterine rupture in subsequent pregnancies),²⁸ the final Dutch paper in 2007 concluded, "Elective cesarean section does not guarantee the improved outcome of the child, but may increase risks for the mother, compared to vaginal delivery,"²⁹ and as early as 2005, a Dutch paper stated that "vaginal breech with strict selection is now preferred."²⁸

Goffinet et al.⁹ stated that in France and Belgium vaginal breech delivery appears to be safe "in places where planned vaginal delivery is a common practice," and Uotila et al.⁸ stated that in Finland it appears to be safe where it has been "traditionally practised." Albrechtsen et al.⁷ stated that in Norway "vaginal delivery is safe for the majority of infants presenting as breech if appropriate protocols for management and adequate skills and equipment for immediate cesarean section and neonatal resuscitation are available."

To add to the breech debate, some practitioners are developing manoeuvres for better enabling the vaginal breech to descend, such as putting the mother on hands and knees or in the upright position³⁰ (Frank Louwen and Anke Reitter,

personal communication, April 2008). It may be appropriate to compare outcomes following vaginal breech delivery with the mother in different positions during labour and delivery. Such a trial would have to take into account lessons from the Term Breech Trial, including caution in how the published results are interpreted.

In the Norwegian experience reported by Albrechtsen, the relative risk of perinatal mortality following vaginal breech delivery compared with non-breech presentation in institutions with 3000 or more births annually was 4.2 (95% CI 3.3 to 5.5) compared with 7.3 (95% CI 6.2 to 8.6) in institutions with fewer than 3000 annual births.²¹ This author concluded that "centralization to larger institutions with more experience and intensive care capacity might be recommended, especially if preterm delivery is suspected."²¹ Nevertheless, it is unclear whether or not the diagnosis of breech presentation in these smaller institutions was made during labour, catching practitioners off guard. Further, while there are implications that a low rate of vaginal delivery at these smaller units may result in limited training,²² they highlight the need for ongoing centralized training for these smaller departments. Albrechtsen and colleagues²¹ concluded that to deliver a woman expecting an uncomplicated vaginal breech delivery by elective Caesarean section because of inexperience should be avoided.

Canada appears to lack centres such as those in Bergen, Paris, and Frankfurt, where breech delivery has been embraced, encouraged, and studied, where medical and midwifery students can learn the manoeuvres used in

breech delivery, and where veteran practitioners can brush up on their skills. It is possible that Canadian clinicians may find it easier to go abroad to get experience and training to update their skills.

Some evidence suggests an association between breech presentation and an increased likelihood of SGA^{31,32} and demonstrates that breech neonates weigh less than vertex controls at the same gestational age.³³ In the PREMODA study,⁹ after removing babies with anomalies from analysis there were no reported deaths associated with small for gestational age or intrauterine growth restriction. However, the protocol for this study recommended against vaginal delivery if the estimated fetal weight on ultrasound examination was under 2500 g. The Term Breech Trial's investigators felt that prior to their trial "no good evidence was available that a term breech fetus that was estimated to weigh less than 2500 g should be delivered by cesarean, if there was no [other] indication."³⁴ It remains difficult to conclude how a fetus with intrauterine growth restriction should be managed or to judge whether the deaths in the Term Breech Trial would have occurred in countries with low perinatal mortality and high resources.

With respect to large babies, Albrechtsen et al. in Norway felt that maintaining an upper weight limit of 4500 g for vaginal breech delivery was justified.⁷ In Norway, MRIs are used to assess maternal pelvimetry. The SOGC guideline recommends an upper weight limit of 4000 g.¹⁰ While pelvimetry is not considered justifiable through research interpretation in the new SOGC recommendations,¹⁰ it may nevertheless be an option in the case of a mother in Canada who chooses to challenge the 4000 g upper limit.

Our survey suggested that 95% of maternity centres in Canada adopted a policy of performing Caesarean section for breech presentation following the Term Breech Trial. In contrast, after the two-year follow-up demonstrated no significant difference in outcome between delivery by Caesarean section and vaginal breech delivery, only one half of the institutions surveyed were aware of the new findings and had considered the implications in their department. Twenty percent of the hospitals surveyed had changed their practice since the two-year follow-up was published, but 55% of the hospitals had experienced little change in practice and did not intend to change over the coming year.

This suggests that the results of the original Term Breech Trial provided validation for a trend that was already under way and is now difficult to undo. Obstetric residents, family doctors, and midwives now rarely perform a vaginal breech delivery during their training.

Prior to our survey, a questionnaire had been sent to all collaborators in the Term Breech Trial, two years after its conclusion, to determine its impact in the different settings.³⁵

Most centres (92.5%) stated that clinical practice had changed to planned Caesarean section for delivery of most or all term breech babies. Our survey corroborates this finding in Canada six to seven years after the trial.

To implement the recommendations in the new SOGC guidelines, we believe that it may be possible to create within a reasonable geographical area a group of experienced practitioners who would either travel to different institutions or make their facilities available for both a breech clinic, where women with a breech presentation could discuss their options, and a breech squad, whose participants would share on-call time with one another to perform vaginal breech deliveries. Seventy percent of heads of obstetrics and nurse managers surveyed do not rule out the possibility of such entities.

Midwife clients tend to demand management of labour and delivery with less intervention and want informed choice, including choice of caregiver. Prior to the Term Breech Trial, experienced midwives were permitted to attend vaginal breech and twin deliveries in some hospitals in Ontario. A resolution to resume the midwifery role of performing vaginal breech delivery with consultation with an obstetrician rather than transfer of care was passed by the Association of Ontario Midwives in May 2009 to provide direction for their board.³⁶ It is important to have this in place as an option because there is published evidence from North America and Britain that some midwifery clients with a breech presentation choose home birth when they are aware that their chosen attendant will have little control once they enter the hospital.^{37,38} In France, midwives attend breech deliveries as primary care providers and perform forceps-assisted deliveries, a skill that has been assumed to be a requirement within the team attending a breech delivery. However, preliminary data from Frankfurt (collected from 2004 to 2008) indicate that use of forceps has not been required in the approximately 300 singleton and 200 twin vaginal breech deliveries conducted when the mother adopts a hands and knees position or leans over the back of the bed (Frank Louwen and Anke Reitter, personal communications April 2008).

The co-chair of the ALARM course has recently queried the "experienced obstetrician" requirement of the SOGC Breech Guideline, suggesting that rural hospitals "with ultrasound and Caesarean section capabilities and very experienced, often foreign-trained, family physicians and midwives . . . should be allowed to perform vaginal breech deliveries if all of the other criteria mentioned are met." He suggested that the requirement that an experienced obstetrician-gynaecologist be present at vaginal breech deliveries could be replaced by a requirement that an experienced *accoucheur* be present.³⁹

CONCLUSIONS

When the findings from the Term Breech Trial suggested that a policy of Caesarean section for breech delivery decreased the risk for the neonate, Canadian institutions were almost five times more likely to adopt such a policy than they were to reintroduce the option of vaginal breech delivery when the difference between the two modes of delivery was rendered insignificant by the same group of investigators. The national and international experience now clearly condones vaginal delivery for breech presentation, a marked departure from the recommendations in 2000. Our survey confirmed gaps in the availability of vaginal breech delivery in the large centres in Canada. Prior to publication of the new SOGC guidelines, there was a general lack of interest in changing back to vaginal breech delivery, despite new evidence, and an initial lack of enthusiasm with regard to the introduction of breech clinics or squads. However, with Canadians requiring evidence-based care, with new research and influence from European researchers, and with positive guidelines and resolutions from the SOGC and the Association of Ontario Midwives, opportunities for a vaginal breech delivery should be greater than they were between 2004 and 2007.

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