

## Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomized multi-center trial (1997-2000)

### Purpose

- Primary research question:
  - For a fetus carried to term who presents as a 'breech' delivery (buttocks or feet appearing first), is a caesarean section (C-section) or a planned vaginal birth better for the baby and the mother?
- Primary outcomes:
  - Perinatal mortality or neonatal mortality at less than 28 days (excluding lethal anomalies)
  - Serious perinatal morbidity (e.g., birth trauma, injury, decreased Apgar score, etc.)
- Secondary outcomes:
  - Maternal mortality or serious maternal morbidity during the first 6 weeks post-partum (e.g. death, hemorrhage, hysterectomy, etc.).
- Perceived clinical importance:
  - Breech presentation is very common, and the mode of delivery that is safest for both the mother and infant had not been ascertained in a large, rigorous randomized trial.

### Background and Context

- Approximately 4% of all infants are in breech presentation; delivery in this position is more difficult, with increased risk of complications to the fetus such as umbilical cord prolapse, hypoxia, and fetal injury.
- Despite increased risks, breech deliveries are usually accomplished without complications and without the need for 'expert assistance' from an experienced, trained clinician or midwife. In the event that expert assistance is needed but not obtained, permanent damage can occur during breech births because to the lack of appropriate and well-timed actions by the birth attendant.
- Historically, vaginal breech deliveries were considered the norm until 1959, when routine C-section was shown to reduce

perinatal mortality and morbidity. <sup>1</sup>

- While there was a general belief that planned C-section was better than a planned vaginal delivery for breech deliveries, evidence was inconclusive because most studies were observational, two small RCTs showed no difference, and evidence suggested that improved neonatal outcomes might occur at the expense of poorer maternal outcomes.

#### **Date and Place Conducted**

- January 9, 1997 - April 21 2000
- 121 centers in 26 countries (Argentina, Australia, Brazil, Canada, Chile, Denmark, Egypt, Finland, Germany, India, Israel, Jordan, Mexico, Netherlands, New Zealand, Pakistan, Palestine, Poland, Portugal, Romania, S. Africa, Switzerland, UK, USA, Yugoslavia, Zimbabwe)

#### **Principal Investigators**

- The Term Breech Trial Collaborative Group
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#### **Sponsored by/source of funding**

- This project was sponsored by a grant from the Canadian Institute of Health Research, Center for Research in Women's Health, Sunnybrook and Women's College Health Sciences Center, and the Department of Obstetrics and Gynecology at the University of Toronto

#### **Size and Design**

##### *Design phase*

- The trial, of considerable size and scope was initiated from a base of collaborators from earlier trial (TERMPROM). It was designed through an extensive protocol development through a consensus workshop by obstetricians recognized as experts in vaginal breech delivery and developed and critiqued by experienced obstetricians globally.
- A pre-trial evaluation, said to be the first of its kind, assessed patients' views regarding participation in an RCT, and found that the majority were agreeable. However, among those who were not agreeable, many said this was due to difficulty with the concept of randomization. <sup>2</sup>

*Design*

- Number of participants:
  - 2088 pregnant women were randomised
    - 1043 assigned to planned caesarean delivery
    - 1045 assigned to planned vaginal delivery
  
- Participant characteristics:
  - Women were eligible if they had a singleton live fetus in a frank or complete breech presentation at term ( $\geq 37$  weeks gestation).
  - Exclusion criteria were contraindications for either delivery method: feto-pelvic disproportion, fetal weight  $\geq 4000$ g, hyperextension of fetal head.
  - Women randomized to both groups were similar upon study entry with no substantial differences by: age, parity, type of breech presentation, gestational age, fetal size/weight, labor assessment methods, country-level perinatal mortality rate, or center-level indicator of standard of care.
  
- Randomization and intervention
  - Participants randomized into the planned caesarean group were scheduled for a C-section at 38 or more weeks' gestation.
  - Participants randomized to the planned vaginal group underwent expectant management until spontaneous labor began.
  - For either groups, participants were reassessed at birth for any signs that necessitate the alteration of their 'planned' delivery method:
    - Planned C-section deliveries reassessed to be cephalic were delivered vaginally
    - Planned vaginal deliveries may have been reassessed given indications to induce labor or perform a C-section.
  - Mothers and babies were followed-up at 6 weeks post partum, and at selected centers 3 month and 2 year follow up to determine the occurrence of complications

**Issues Encountered During the Trial <sup>3</sup>**

- During the course of the trial, one participating center could not provide the appropriate level of care for patients in the study and the center's participation was discontinued: following this experience a screening tool assessed level of care at participating centers.

- Ease in obtaining local ethics committee approval ranged widely and experiences varied by location and country. Because of this, one country (UK) instituted a mechanism for national ethical approval to better facilitate the process. Other centers (Africa, Asia) adapted the consent process to local cultural needs and practices. In two Asian centers the local investigators felt it create undue anxiety to the patient to explain that the doctors did not know which method was better and therefore unethical. Some centers instituted a policy of verbal consent because many participants would be illiterate.
- Some centers dropped out due to hospital closures or “diminished local enthusiasm” for recruitment.
- The study was initially planned to span a 5 year period enrolling as many as 2800 women. However, better perinatal outcomes were identified at the first planned interim analysis and confirmed at the second planned interim analysis, thereby leading the independent Data Monitoring Committee to recommend stopping the trial early.

## Findings

- Of the 1041 women assigned plan C-section, 90.4% delivered by C-section. Of the 1042 women assigned to vaginal birth, 56.7% delivered vaginally.
- Perinatal mortality, neonatal mortality, or serious neonatal morbidity was lower for the planned C-section group (17/1039) than for the planned vaginal group (52/1039). (RR= 0.33, 95% CI 0.19 - 0.56). Findings were consistent for mortality alone (0.23, 0.07-0.81) and serious neonatal morbidity (0.36, 0.19-0.65).
- Secondary analyses found adverse perinatal outcomes associated with labor augmentation, birth weight <2.8 kg, and a longer time between pushing and delivery; the presence of an experienced clinician reduced the risk of adverse perinatal outcome.<sup>4</sup>
- The trial reported no difference between groups for maternal mortality or serious maternal morbidity (C-section, 41/1041 versus vaginal, 33/1042, RR=1.24, 95% CI 0.79 – 1.95).
  - However, these new data combined into a meta-analysis with the previous trials showed the risk to the mother becomes significant (RR 1.29, 1.02-1.61).

- Differing effects were found among high perinatal mortality countries versus low perinatal mortality countries such that:
  - the risk reduction of planned C-section was greater in low perinatal mortality countries whereas high perinatal mortality rate countries had a smaller reduction in neonatal/perinatal mortality/serious morbidity.
- At a 3-month follow-up to examine post-partum outcomes, few differences were found except that women in the planned- C-section delivery group were less likely to report urinary incontinence than those in the planned vaginal birth group.<sup>5</sup>
- Upon 2 years of follow-up, no differences appeared among 1159 mothers from 85 of the centers in terms of factors such as breastfeeding, health, mental health. No difference was found after 2 years of follow-up among children in terms of death or neurodevelopmental delays.<sup>6, 7</sup>

## Impact

- The publication of the trial results met considerable discussion, both positive and negative:<sup>8-16</sup>
  - Critics questioned the place of evidence-based medicine for answering 'complex' phenomena (i.e., those which incorporate complex steps and in which human heterogeneity in skills is expected).
  - Question was raised to the appropriateness of applying these results to broader populations, the appropriateness of subgroup analyses in understanding this 'complex' phenomenon, and the threat of practitioners 'lowering' standards to a 'average model' of care in order to follow a standard protocol.
  - Furthermore, in following a trial protocol, the appropriateness and effect on practitioners was questioned since it may alter practice outside their 'level of comfort' which may effect practitioners actions and methodology. Because of the equipoise of the trial setting, protection from medico-legal liability may alter the 'comfort level' of the practitioners.
  - Further criticisms included the use of short-term and combined trial endpoints as misleading, lack of generalizability, the inappropriateness of intention to treat analyses, the impossibility of masking to allocation, and discomfort in the impact of one randomized trial in influencing a standard of care. Much of the criticisms were refuted by the trial authors as incorrect or misinterpretations.

- The term breech trial had an immediate impact on the management of term breech deliveries with policies changed in accordance with the trials findings.
  - A follow-up survey of 80 participating centers from 23 countries found that in 92% had changes clinical practice to plan cesarean section for all term breech policies with 66% of these reporting no difficulties with the implementation of this policy and 85% indicating that cost would not affect this policy change.<sup>17</sup>
  - Professional organizations of obstetricians in countries not involved in the trial called for evaluations of their current practices and safety of these procedures to consider the applicability of the study findings to their countries.<sup>18; 19</sup>
  - Several comparison studies showed alteration of clinical practice via examining rates of vaginal breech versus C-section in various countries (e.g., New Zealand, Australia).<sup>20; 21</sup>
  - The rapidity of its uptake was likely influenced by the pressure of potential medical-legal implications for practitioners not adhering to the best practices.
- For practicing midwives, the trial had negative implications. There was concern that policy formed out of evidence-based principals would lead to a reduction of the role of the midwife during intra-partum care, the loss of continuity-of-care in the birthing process, and constraint in women's choice in delivery.<sup>22</sup>

### Unresolved issues<sup>23; 24</sup>

- As cesarean section for term breech deliveries becomes the norm and vaginal breech becomes less common, there is the concern of loss of clinicians skilled in breech deliveries because that skill is dependent on training and experience. The effect of a change in practice therefore may alter the risk associated with the practice itself that could result in an increased risk to some women.
  - For some women C-section is not advisable or feasible.
  - The trial results are not inclusive of non-term breech pregnancies (e.g. multiple birth, pre-term breech birth)
- The public health implications of increased rates of C-section are unknown, such as postoperative infections or resistant bacteria following antibiotic prophylaxis, or increased morbidity and mortality.

- Some evidence (data from the Netherlands<sup>25; 26</sup>) found no accompanying rise in maternal morbidity/mortality occurred that was of potential concern. Another concern is the risk of prior C-section on future pregnancies.
  - The international implications of a policy of systematic C-section and international pressure was said to place undue burden on developing countries, where services may be unavailable, have unrealistic cost, or performed by ill-trained staff.
  - Where social pressure for high parity exists, policies that increase C-section create added risk of rupture of C-section scar, dangers of multiple C-sections.

## Summary

The Term Breech trial, a multi-center trial across 121 centers in 26 countries randomizing 2088 women to 'planned C-section' or 'planned vaginal' deliveries found during interim analyses that C-section was associated with a reduced risk of perinatal morbidity and mortality. This controversial trial made a dramatic impact on practice and raised further questions beyond its scope. Rapid change in clinical practice occurred in many locations, although not universally, as some desired more evidence and others were reticent to accept the trials results as conclusive. Despite the deliberate trial process of consensus building and expert consultation and review, the trial results were met with both acclaim, criticism and dispute. There was concern that policy formed out of the trial's results would lead to a reduction of the role of the midwife during intra-partum care, the potential restraint of a in women's choice in delivery, and the loss of continuity-of-care in the birthing process that midwives would deliver. The rapid change in practice following the trial led to concern of that clinical skill in vaginal delivery of breech births would decrease, as well as unintended increases in adverse outcomes associated with additional C-sections.

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