

Critique of the Term Breech Trial

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The term breech trial (TBT) (Hannah, et al. 2000) was designed to conclusively determine if vaginal or cesarean section was the best mode of delivery for breech presentation. Previous studies suffered from small sample size, lack of randomization, and unclear inclusion protocols and outcome measures. The term breech trial was a randomized multi-center trial that included 2083 women from 121 centers in 26 countries. Inclusion criteria were singleton live fetus in frank or complete presentation at term (≥ 37 weeks). Exclusion criteria included fetopelvic disproportion, fetal macrosomia (or estimated weight ≥ 4000 grams), hyperextension of fetal head (undefined), clinician determined fetal anomaly or other mechanical condition, or a condition contraindicating vaginal delivery (e.g. placenta previa).

Planned cesarean sections were scheduled for 38 weeks gestation or more. Approved intervention included induction of labor, amniotomy or augmentation of labor for standard obstetrical indications, fetal heart monitoring intermittently or continuously, cervical dilation at least 0.5 cm/hour after the onset of active labor, descent of breech to the pelvic floor within two hours of full dilatation during second stage of labor, and delivery within one hour of active pushing. If there were fetal heart rate abnormalities or lack of progress, a cesarean was performed. If the baby were birthed vaginally, the baby was allowed to birth spontaneously up to the umbilicus, then controlled delivery of

the after-coming head either with forceps or Mauriceau-Smellie-Veit maneuver occurred. Total breech extraction was not permitted.

The primary outcome was perinatal or neonatal mortality before 28 days or neonatal morbidity (birth trauma, seizures, Apgar score <4 at five minutes; cord-blood base deficit at least 15, hypotonia two hours, stupor, decreased response to pain, coma, intubation and ventilation, tube feeding, and admission to neonatal intensive care unit). The secondary outcome was maternal mortality or morbidity during six weeks post-partum. The study found planned cesarean section produced lower infant mortality and morbidity for babies in industrialized countries. There was no difference in maternal mortality or morbidity between vaginal and cesarean groups.

While this study is accepted as the gold standard in breech delivery outcome research, it is limited in several ways: 1) Inherent biases of the study design, 2) Recruitment of participants, 3) Categorical data analysis, 4) Use of non-parametric tests, 5) Presentation of initial findings, and 6) Presentation of follow-up findings.

1) Biases of Study Design

To participate in this randomized controlled clinical trial women had to agree to be randomly assigned to either the cesarean or to the vaginal birth group. This introduces a monumental bias into the study that cannot be overcome in the analysis section. If a woman is neutral about mode of delivery,

she is not committed to a vaginal birth and may not be psychologically prepared for the demands thereof. This biases the study toward a Type I error (rejecting the null-hypothesis although it is true). A more appropriate design would be a cohort study where women self-select intervention. This is effectually a naturalistic experiment. While the cohort study is not randomized, the authors of the TBT found randomization did not afford the anticipated benefits since the trial was analyzed by intent to treat, but “women randomized to the planned vaginal birth group had a high rate of cesarean delivery, which would have reduced our ability of finding an association between cesarean delivery and adverse outcomes, if one existed” (Hannah, et al. 2002:1830).

2) Recruitment

Hewson et al. (2002) review the methodology of the TBT and note a disproportionate number of centers (61) in the English-speaking industrialized world versus the non-industrialized third world (27). However, over half (1161) of the individuals participating in the study come from the developing world. This suggests the English speaking countries had difficulty recruiting participants and needed additional sites to increase their numbers. The difficulty in recruiting participants in English speaking countries suggests the participants may not be representative of the target population, therefore results must be interpreted with caution.

3) Categorical data analysis

Categorical data analysis was used to analyze continuous data in this study. The basic problem with categorical data analysis applied to continuous data is that an emic perspective is imposed upon the data. For instance, WHO identifies a low perinatal mortality rate as $\leq 20/1000$ while a high perinatal mortality rate is $>20/1000$. One death per 1000 switches a nation from one status to the other. It is better to first conduct a multiple linear-regression analysis to determine natural categories within the data rather than just using categorical analysis with continuous data.

4) Use of non-parametric tests

The TBT was stopped early due to disproportionate adverse outcomes between groups. The study was originally designed as a single tailed test, but the intermediate analysis was designed as a two tailed test. Upon termination of the study, the data did not conform to the assumptions of parametric tests (normalcy, variance, and linearity) and therefore had to be analyzed with non-parametric tests. While non-parametric tests are valid and do offer statistically significant findings, they are less generalizable since the sample does not conform to the population profile.

5) Presentation of Initial Findings

The study's initial conclusions read "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" (Hannah, et al. 2000:1375) However, when the data were analyzed comparing outcomes for

countries with low perinatal mortality rates and high perinatal mortality rates this finding held only for countries with low mortality rates (i.e. the industrialized world). For the developing world (perinatal mortality rate >20/1000) there is no statistical difference between morbidity and mortality outcomes for cesarean babies and vaginally delivered babies (RR=0.66, 95% CI 0.35-1.24, p=0.13).

Thus, there are two competing findings in this study although this is glossed over. The reasons for the difference in response to delivery methods in the developed world and in the developing world are not hypothesized. Are clinicians in the developing world inexperienced at cesarean sections? Are clinicians in the developed world insufficiently competent at vaginal breech deliveries? Why is there a difference?

6) Presentation of Follow-Up Findings

At the three month follow up of maternal morbidity for the Term Breech Trial (Hannah, et al. 2002) 1596 or 1940 women from 110 centers were surveyed. The first page summary conclusion reads "Planned cesarean delivery for pregnancies with breech presentation at term may result in a lower risk of incontinence and is not associated with an increased risk of other problems for women at 3 months post partum, although the effect on longer-term outcomes is uncertain" (Hannah, et al. 2002:1822). While this conclusion seems to advocate cesarean section, buried within the text of the article are additional differences between the two groups, not least of which was that women in the cesarean section group reported they did not like being in the trial because they did not

like the method of delivery to which they were assigned (RR=2.0; 95% CI 1.31-3.04; P=.001). Additionally, fewer cesarean sectioned women breastfed their baby within a few hours of birth (RR=0.94; 95% CI, 0.89-1.00; P=.05), women in the cesarean group had more pain on the outside of the abdomen (RR=1.76; 95% CI, 1.24-2.50; P=.002) or deep in the abdomen (RR=1.89; 95% CI, 1.29-2.79; P<.001) than did vaginal birth women, and fewer c-sectioned women had pain in the bottom or genital area (RR=0.32; 95% CI, 0.18-0.58, P<.001).

The Term Breech Trial offers an opportunity to critically interpret cultural assumptions about birth and about “good” birth outcomes such as long term v. short term outcomes, maternal v. infant outcomes, and the assumed benefits of a “controlled” environment over a naturalistic environment. Although the controlled randomized clinical trial is posited to be an objective measure of reality, clearly it is still subject to personal and cultural biases in design and interpretation. I suggest the major contribution of this study is not validation of superior birth outcomes for the cesarean group as the article concludes, but rather reinforcement of the importance of reading all journal articles with a critical eye.

References

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