Why Vaginal Breech Delivery Should Still Be Offered: A Response

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In this issue of the Journal of Obstetrics and Gynaecology Canada, Dr Savas Menticoglou provides evidence to answer the question "Is there still a place for an obstetrician to discuss the option of vaginal breech delivery?" In his thought-provoking commentary,[1] he refers to recent reports of experience in carefully selected vaginal breech births from single centres, as well as data from national registries. Appropriately, he pays particular attention to key publications[2,3] of the Term Breech Trial (TBT).

The TBT was a multicentre randomized clinical trial (RCT) conducted in 121 centres in 26 countries. It involved 2088 women with a singleton pregnancy and a frank or complete breech presentation who were assigned to planned Caesarean section (PCS) or planned vaginal birth (PVB), with analysis on an intent-to-treat basis. The publications related to the TBT provide information about prospectively collected data that were least likely to be influenced by known prognostic factors and unknown confounders. The completion of this influential research, led by the University of Toronto's Dr Mary Hannah, was a remarkable achievement. The first report[2] concluded that PCS is better for the term breech fetus, on the basis of a significant improvement in the primary outcome (a composite of perinatal mortality, neonatal mortality, or serious neonatal morbidity). About half of the women participating in the TBT came from countries with a low perinatal mortality rate (PMR) (≤ 20 per 1000) and half from countries with a high PMR (> 20 per 1000). The reduction in risk with PCS was much greater in countries with low PMR (0.4 % vs. 5.7 %; $P < 0.0001$) than in countries with a high PMR (2.9% vs. 4.4 %; $P = 0.13$). This surprising and significant interaction was accounted for by the fact that the serious neonatal morbidity among randomized patients was not lower in countries reported to have a low PMR than in those with a high PMR (2.7 % vs. 2.4 %). On the basis of this report of short-term outcomes, CS became the approach recommended to women with a term breech fetus.[4–6]

A planned two-year follow-up of 923 infants from 85 TBT centres, where follow-up was expected to be 80% or more, was published in 2004.[3] The conclusion was that infants delivered by PCS did not have a lower risk of death or neurodevelopmental delay at two years of age than did those delivered by PVB (3.1 % vs. 2.8%; $P = 0.85$). The serious short-term morbidities identified in the initial report[2] disappeared in 17 of 18 newborns. This is not unlike the findings regarding worrisome newborn morbidities in the initial[7] and follow-up[8] reports of the Dublin RCT of electronic fetal heart rate monitoring. There has been little momentum[9,10] to alter any recommendations or guidelines that were developed after the original TBT report.[2]

Because his comments are directed to Canadian readers, Dr Menticoglou has focused on the results from countries with low PMR. He has reasoned that each of the three deaths in the trial from these countries, all in the PVB group, should have been excluded from the analysis. I agree with his assessment of death number two (in Table 4),[2] but not of the other two deaths, because an experienced clinician was present at the birth and was responsible for the decisions in care. In the original TBT report,[2] a sub-analysis was carried out excluding the two deaths (both in the PVB group) that occurred prior to randomization, one of which was death number two. This did not change the original conclusion. Such an approach was reasonable in addressing the randomization of a subject in deference to eligibility criteria. A better methodologic alternative would have been to have the data monitoring committee, blind to group assessment, appraise all questionably eligible randomized subjects before analysis and make a decision to include or exclude

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them. This may have been done, but it was not made explicit in the report.

Retrospectively removing subjects from an analysis after revealing group assignment eliminates the strength of an RCT in reducing selection bias (balancing known risks and unknown confounders). Caesarean sections can also be challenging, but no subjects with PCS and an adverse outcome (who may have had their care provided under less than ideal circumstances) were retrospectively excluded in the TBT report. For example, in a later TBT publication there is a description (in Table 2) of a subject randomized to PCS who experienced an adverse outcome after a prolonged augmented labour.[11] In fact, the inclusion of any of the three deaths after PCS in the original TBT report (see Table 4 of the report)[2] could similarly be questioned. Analysis by intent-to-treat is the basis of an effectiveness, pragmatic, or management trial,[12] answering the question "does this treatment work in real life practice?" The alternative, seeking the ideal patient with the "best" clinician, gives us an efficacy or explanatory trial, answering the question "can this treatment ever work?" Generalizing the results then becomes an issue.

Despite the two-year follow-up data, the initial overall significant reduction in PMR associated with PCS remains a substantive issue.[2] Death is absolute. If we consider the two deaths in the PVB group from countries with a low PMR to be preventable by PCS, this suggests that about 250 planned Caesarean sections are necessary to prevent one perinatal death. Dr Menticoglou provides a detailed review of non-randomized studies from the past decade (shown in his Table), and argues that the figure is closer to 400 required Caesarean sections. This review, however meticulous, is nevertheless based on retrospective single centre studies and reviews of databases and registry reviews that are more open to bias, as described previously. In countries with a high PMR (and low resources), fewer than 90 Caesarean sections may be needed to prevent one death.

Dr Menticoglou's commentary in this issue of JOGC[1] appropriately points out the maternal morbidities and risks associated with Caesarean section. He refers to Verhoeven et al.,[13] who estimated that there have been 8500 additional elective Caesarean sections performed in the Netherlands for term breech since the first TBT report. Although acknowledging that these may have prevented 19 perinatal losses, they have also attributed four avoidable maternal deaths to these Caesarean sections. Such a maternal mortality rate is at odds with reports indicating that elective scheduled Caesarean sections have much lower maternal risks,[14] perhaps even than vaginal delivery.[15] The TBT reports of initial,[2] three-month,[16] and two-year maternal morbidity[17] showed remarkably little difference between the PCS and PVB approaches.

I must declare my own bias. I offer external cephalic version to patients, although I am discouraged by my low rate of success. I consider myself experienced in vaginal breech birth and offered it before the TBT. I truly fear an entrapment of the after-coming head that will not respond to traction with Piper forceps, although I have not experienced this. The two centres where I practised during the TBT did not enrol patients in the TBT. I was personally concerned that the planned clinically important reduction in primary outcome (from 0.8 % to 0.1%) with PCS, on which the sample size was calculated, was not attainable. In the end, that reduction in relative risk was not achieved, but because there was a higher primary outcome rate than anticipated, a greater reduction in absolute risk was statistically significant and clinically meaningful.

Dr Menticoglou describes three aspects of vaginal breech delivery that make it more dangerous to the fetus than normal cephalic delivery, and recommends ways to make vaginal breech birth safer. First, the frequency of adverse perinatal outcomes by actual method of delivery reported in the TBT increased progressively from pre-labour CS (0.9%) to CS during early labour (1.2%), to CS during active labour (3.0%), and was highest with vaginal birth (6.2%).[11] Dr Menticoglou notes that there is a risk of cord prolapse before and during labour. He speculates that a protocol of serial ultrasound examinations, preferably vaginal, beginning near term in pregnancies with breech presentation can identify cord presentation. This finding would lead to CS before labour. He infers that this approach will reduce the frequency of cord prolapse. He also speculates that a vaginal ultrasound examination during labour can be helpful in ruling out an occult cord presentation not identified on pelvic examination. This innovative approach certainly may be successful, but its effectiveness and feasibility remain to be confirmed in more than case reports.

Second, it is without question that for PVB an obstetrician should be continuously present during descent and pushing in the second stage of labour, which should be conducted as a double set-up.

Third, every obstetrician fears entrapment of the aftercoming head. Dr Menticoglou advocates a role for symphysiotomy, an operation in which the fibrocartilaginous symphysis pubis is divided with a scalpel. It can be carried out rapidly under local anaesthesia. Careful support of the parturient's legs is essential. The procedure has been well described in published articles, some of which include diagrams.[18–20] Although widely practised in the developing world, it has rarely been used in North America[21] and Europe.[22] Recent case reports demonstrate