# CORRESPONDENCE

### Term breech trial

Sir—The report by Mary Hannah and colleagues (Oct 21, p 1375) will go down as a landmark paper in obstetrics. At least in more-developed countries, it will change obstetric practice permanently and push assisted vaginal delivery of singleton term breech fetuses into the history books. Before universal acceptance, however, some queries need clarification.

Of the 1042 women assigned planned vaginal delivery, any form of objective adequacy assessment of pelvic magnetic resonance (radiography, imaging, or computed tomography pelvimetry) was done in only 102 (9.8%) women. 226 women in the group had emergency caesarean sections because of suspected fetopelvic disproportion or non-progress of labour. Whether some of the caesarean sections were decided after clinicians knew the results of radiographic pelvimetry is unclear. The safety of vaginal breech birth depends on the stringency of case selection, which includes pelvic adequacy. There is no good evidence to support the view that pelvic size affects perinatal mortality or the rate of successful vaginal breech delivery,<sup>2</sup> but use of radiographic pelvimetry has not been assessed by randomised trial. In 1997, van Loon and colleagues3 reported the effects on clinical outcome of magnetic resonance pelvimetry. The availability of the pelvimetry findings led to increased vaginal breech birth rate, despite more elective caesarean sections in the study group, with no significant difference in perinatal outcome between the groups. Hannah and colleagues' trial would have been more robust if objective pelvic adequacy was confirmed by radiographic pelvimetry before inclusion.

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- 1 Hannah ME, Hannah WJ, Hewson SA, Hodnert ED, Saigal S, Willan AR, for the Term Breech Trial Collaborative Group. Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial. Lancet 2000; 356: 1375–83.
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Randomised controlled trial of magneticresonance pelvimetry in breech presentation at term. *Lancet* 1997; 350: 1799–804.

Sir—Mary Hannah and colleagues' show that planned caesarean section is of clear benefit over planned vaginal breech for perinatal mortality, neonatal mortality, or serious neonatal morbidity. Serious maternal complications are similar between the two groups. They clarify that caesarean section is best for breech babies at term, and that a policy of planned vaginal birth should not be encouraged for singleton fetuses.

We wonder whether the same principle applies to the entire breech population at term. 20-30% of such presentations remain undiagnosed until after the onset of labour.2.3 We did a study on undiagnosed breech presentations.4 Undiagnosed breech presentations are more likely to deliver vaginally with no excess of neonatal morbidity than those diagnosed in the antenatal clinic. We suggest that the progress of labour, measured by cervical dilatation and descent of the breech into the pelvis, is a more efficient predictor of a successful vaginal delivery than selection of women antenatally. In Hannah and colleagues' trial, 59 women delivered vaginally in the planned caesarean-section group since caesarean was not possible because of imminent vaginal delivery. We think that this subgroup might be analogous to undiagnosed breeches because the progress of labour has convinced the obstetrician of the method of delivery, and would like to know the outcome analysis of this subgroup.

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Sir—Mary Hannah and colleagues' rightly say that their finding that caesarean section is better than planned vaginal delivery for breech presentation might disappoint many obstetricians. However, we have some concerns about their methods and interpretation of the results.

Presumably growth-retarded fetuses were randomised or fetal-growth retardation was not recognised during pregnancy. Randomisation of such fetuses gives rise to some ethical concerns, especially planned vaginal deliveries, since pregnancy can be prolonged when delivery would have been necessary. Inclusion of presumably growth-retarded fetuses could explain some of the perinatal and neonatal deaths; seven fetuses that weighed 1150-2550 g who died were probably growth retarded. In five other deaths, birthweight of 2700-3050 g with difficult vaginal delivery, gestational age of 41 weeks or more, and sudden disappearance of fetal heart tones during labour suggest fetuses appropriate for gestational age could be growth retarded. In term breech fetuses, perinatal mortality because of hypoxia those weighing highest in 2500-3000 g.<sup>2,3</sup>

fetal heart-rate Intermittent monitoring could explain the three fetal deaths that had sudden heart-tone in Hannah disappearance colleagues' study. Continuous tracing show suspicious if not should pathological signs. Vaginal delivery in a with heart-rate fetus breech. abnormalities can be fatal.4 In two cases in the planned caesarean section group, spinal-cord injury and basal skull facture occurred. If planned caesarean-section is to be protective for breech fetuses, such injuries should not happen.

We did a multivariate logistic regression analysis of risk factors for 5 min Apgar score of 6 or less in 2952 singleton term breech neonates, excluding those with fatal malformations and prelabour deaths. Independent risk factors were male sex, birthweight lower than 2500 g, single mother, proteinuria in pregnancy, non-frank breech presentation in elective caesarean section, and frank breech presentation in urgent caesarean section. Vaginal delivery was not a risk factor, despite higher perinatal and neonatal mortality

in that group. Caesarean section rate was 30.4%. Overall perinatal mortality (>500 g) was less than ten.

We have noted that breech fetuses appropriate for gestational age had significantly lower pH, a higher partial pressure of carbon dioxide, and greater base deficit in mixed capillary blood than vertex fetuses at the end of the first stage of labour. Despite some differences in acid-base and gas values in the umbilical artery and vein between the breech and vertex neonates, after delivery the frequency of birth hypoxia did not differ.

Despite the size of Hannah and colleagues' study and efforts to avoid biases, their conclusions are disputable and not generalisable to all term breech fetuses. They do show that vaginal delivery is not appropriate for compromised fetuses without proper monitoring, that pregnancy should not be prolonged without proper fetal surveillance and care, and that monitoring of heart rate during labour is essential. Even a caesarean section did not protect a breech fetus against serious fetal trauma.'

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- 1 Hannah ME, Hannah WJ, Hewson SA, Hodnett ED, Daigal S, Willan AR, for the Term Breech Trial Collaborative Group. Planned cesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial. *Lancet* 2000; 356: 1375–83.
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Sir—There are three issues in Mary Hannah and colleagues' report on term breech delivery that should be addressed.

The first is the accuracy of the diagnosis of fetopelvic disproportion. Hannah and colleagues state that women were excluded if there was evidence of fetopelvic disproportion. However six of the 16 deaths were associated with difficult vaginal delivery due to clinical fetopelvic disproportion, and these fetuses should have been excluded before randomisation as cases of existing fetopelvic disproportion.

Second, we are unsure about the method of estimating fetal body weight. The investigators state that fetuses judged to be clinically large or to have an estimated fetal weight of 4000 g or more were excluded before enrolment. Yet, 32 (3·1%) of the neonates in the planned caesarean section group and 59 (5·8%) in the planned vaginal birth group weighed more than 4000 g. This high number of fetuses weighing more than 400 g could have affected the poor outcome in the planned vaginal delivery group.

Third, the condition of the umbilical cord was not assessed. Many workers have noted that umbilical-cord disorders can cause serious complications; tight nuchal cord and shoulder dystocia are a potentially catastrophic combination,2,3 and symptomatic nuchal cords that are identified before labour as being extremely tight or having multiple loops, might be associated with a subclinical deficit in neurodevelopperformance.4 mental careful assessment of the cord by colour doppler ultrasonography' would lower the incidence of cord disorders such as cord prolapse, and fetal heartrate abnormalities in planned vaginal births.

The risk in planned vaginal birth might decline in the future when obstetricians can appropriately assess fetopelvic disproportion and umbilical-cord disorders for breech presentation at term

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- 1 Hannah ME, Hannah WJ, Hewson SA, Hodnett ED, Saigal S, Willan AR, for the Term Breech Trial Collaborative Group. Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial. *Lancet* 2000; 356: 1375-83.
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Sir—The report by Mary Hannah and colleagues' will hopefully give some peace of mind to many young obstetricians. The increase of caesarcansection rates in many more-developed countries has been attributed to the

improved safety of surgery and to the fear of medicolegal actions, but also to young obstetricians' lack of experience in operative vaginal deliveries. Yet, they cannot be blamed, since the performance of these procedures is declining sharply, and it may well be that during his or her training the specialist of tomorrow will see no forceps extraction or breech delivery.

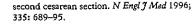
Many obstetricians are reluctant to plan caesarean sections even in the presence of fetal or maternal risk because they see the surgical option as a sort of extrema ratio. This approach is in contrast to the results of several studies that clearly show that planned caesearan section is better than the same surgery done during labour. Since operative vaginal deliveries are probably not associated with unfavourable obstetric outcomes, whose rates are similar for caesarean sections during labour, the key issue is to prevent a difficult labour from occurring. Indeed, rates of intracranial injury2 and encephalopathy of neonates,3 as well as major maternal complications,4 are all significantly reduced by a thoughtful adoption of planned caesarean sections.

Inquiries led by politicians, health economists, and consumers against the alleged abuse of caesarean sections by incompetent or dishonest doctors are increasing. We hope that good data, such as those reported by Hannah and colleagues will help to clarify a subject that is still matter of debate in the wards as well as in the courts.

Our society is ready to pay for thousands of occult blood or mammographic screening tests per decade to prevent one colorectal and one breast cancer death respectively; we believe that few will pretend that the avoidance of the death or serious morbidity of a baby for every additional 14 planned caesarean sections done is not worthwhile.

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Sir—Mary Hannah and colleagues' report' conclude that planned caesarean section is better than planned vaginal birth for term breech fetuses. After a critical review, however, we think that they should explore some points before we can support their conclusion.

121 centres in 26 different countries were included. The heterogeneous group of investigators might have affected the results. In addition, Hannah and colleagues should discuss in more detail the ethical issues of randomising 488 patients after the second interim analysis, which showed an important difference for treatment results between groups.

Assessment of adequacy of pelvis was clinical in only 90% of women, which could have led to the higher incidence of fetopelvic disproportion or failure in labour (50·1%). Use of a more adequate method of pelvic assessment could have lowered the inclusion rate of fetuses with fetopelvic disproportion and modified the findings.

Some of the 16 stillbirths and neonatal deaths can be excluded as not associated with the delivery method (Hannah and colleagues' table 4): cases number 2 and 15 died before enrolment, number six died during sleep, number 7 had a congenital died anomaly, number 9 after developing severe vomiting diarrhoea, and number 16 had a ruptured myelomeningocele. Recalculation of the perinatal and neonatal mortality is two (0.20%) of 1038 for caesarean section and eight (0.77%) of 1034 for vaginal delivery (p=0.12).

More discussion is needed about the differences between the groups for birthweight more than 4000 g, which might affect results. Moreover, Hannah and colleagues do not make it clear whether their conclusion is generalisable to countries with high perinatal mortality rates and whether they compared the body-mass index, and obstetric disorders (diabetes, hypertension, &c) between the groups.

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#### Authors' reply

Sir-In the trial, there were no interactions between treatment group and any of the baseline variables recorded at the time of randomisation, except for country, as defined by the national perinatal morbidity rate (≤20 vs >20 of 1000). The reduction in risk of the primaty outcome with planned caesarean compared with that for planned vaginal birth was similar irrespective of subgroup. Specifically, the reduction in risk of the primary outcome with planned caesarean was similar if parity was none, one to four, or more than four, was similar if the woman was in or not in labour at the time of randomisation, or if the fetus was judged to be small or of average size, or if ultrasonography was used to judge the size of the fetus compared with clinical assessment, or if the pelvis was assessed clinically or radiologically, and so on. protocol did not radiographic pelvic assessment since we were unaware of any evidence that this technology would reduce adverse perinatal outcomes and it was not the standard of care among most of the participating centres.

We do not believe that the benefits planned caesarean from concentrated among a subgroup of large babies. More fetuses weighed more than 4000 g at delivery in the planned vaginal birth group than in the caesarean group because delivery was later in that group and the fetuses had more time to grow. Most of the large babies in that group (47 [79.7%] of 59) were delivered by caesarean. Nor do we believe that the benefits from planned caesarean were concentrated among a subgroup of growth-restricted fetuses. Women were not eligible to participate in the study if we thought the fetus could not tolerate labour or if a mechanical difficulty at delivery was anticipted (eg, asymmetric growth restriction). We assessed around 60% of women with ultrasonography before entry, and planned caesarean was similarly beneficial if ultrasound or clinical assessment was used. The baby weighing 1150 g was a macerated stillbirth of a set of preterm twins that presented in labour, without previous ultrasonography; the other fetus was born alive, weighing 2300 g. The pregnancy was thought to have been at term with a singleton live fetus. Only a few women had obstetric difficulties in the study (29 had gestational diabetes, nine had non-gestational diabetes, 101 had hypertension, 54 had a previous caesarean), and these were similar between groups.

Among more-developed countries, 31 babies had a primary outcome; 28 had serious morbidity and three died. Given the low mortality rate, we believe that it would be more helpful to review rates of serious neonatal morbidity than mortality to assess the applicability of the study findings to other settings in moredeveloped nations. We agree that clinicians need to continue to be educated as to how to undertake safely a vaginal breech delivery, since such delivery will continue to occur despite a widespread policy of planned caesarean. However, earlier diagnosis of the breech and better training in external cephalic version would also be helpful.

We did not request that all women undergoing labour with a breech have continuous electronic fetal heart-rate monitoring since we were unaware of evidence to support this. Among the 1538 women who went into labour during the trial, 523 (34.0%) had continuous monitoring. In response to Tanja Premru-Sršen, we reanalysed the data after excluding the vaginal breech which continuous deliveries in monitoring was not the principal method of monitoring. The results did not change. The two intrapartum stillbirths not associated with difficult delivery had undergone intermittent monitoring. Whether continuous monitoring would have prevented these two deaths is a matter of speculation.

We did not find planned caesarean to be less effective if the diagnosis of breech presentation was made in labour. In response to Wong Cheong Leung and Ting Chung Pun, we repeated the test for interaction after subdividing labour by whether it was early or active at the time of randomisation, and the results did not change. Two babies had an adverse outcome among the 59 women in the planned caesarean group who delivered vaginally because a caesarean could not be organised. Although our protocol did not require a check for cord complications before randomisation, none of the 14 babies with cord prolapse had an adverse outcome.

We can reassure João Cunha-Filho and Eduardo Passos about the ethical conduct of the Term Breech Trial. We took several months to obtain complete data for the first 1600 women enrolled (ie, those assessed for the second interm analysis), check for inconsistencies, and verify concerns with the centres. During this time, 488 additional women were recruited. The results of the second interm analysis were reviewed by the data monitoring committee on April 20, 2000; their recommendation was presented to the steering committee by teleconference on April 21, 2000; randomisation was stopped that day.

We did not exclude deaths thought to be due to other factors than the delivery since exclusions after randomisation may lead to bias. Also, the additional benefits of a policy of planned caesarean at term might be labour and prolonged because pregnancy are avoided, not just because difficult delivery is reduced.

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Sir-As a doctor in a less-developedcountry clinic that has no surgical facilities, I found the conclusion of Mary Hannah and colleagues' report' very worrying. They imply that planned caesarean section should be the worldwide standard method for delivery of singleton breech fetuses.

In the many less-wealthy countries in which most of the world's population live and give birth, the availability of caesarean section is limited. Women may have to take long journeys on difficult roads, if and when transport is available. There can also be high financial cost. Surgery is not free to poor people, only to the well-off or well insured. Facilities and expertise for caesarean sections on exhausted patients might not yield the optimistically low mortality and morbidity suggested by Hannah and colleagues.

I suspect that may of the caesareans in less-developed countries are not done by specialist-trained obstetricians, but by medical generalists. 39 caesareans (one or more of whom may die from the delayed surgery or sepsis) to improve one fetal outcome sounds like a very shocking price to pay for those of us who see women every day who expect 15-20% of their children to die in infancy despite our best efforts to support them.

The survivors of surgery have to deal with the prospect of the next five to ten pregnancies in their normal environment, hampered by the worry that their scar is going to rupture and require further, even more urgent, surgical intervention or lead to death. Some women who have had three or four children delivered, some of whom have died because of the high infant mortality in their countries, find that after the second or third caesarean, surgeons decided they must quietly tie the fallopian tubes to avoid future surgery made difficult through previous assorted scars. In The Gambia, the average woman is expected to have six or seven babies. To have fewer is commonly a of serious anxiety embarrassment, both to her and to her family. Loss of a child is a source of grief not of shame. Loss of fertility is another matter.

Very few of the trial's collaborative group come from the resource-poor areas of the world, where safe surgery is so hard to find.

Before the struggling nations of the world are shamed (unnecessarily) into inflicting a breech-caesarean policy on their women, I suggest a major rejoinder to the article be published. Skills for vaginal delivering of breech babies must not be lost, and doctors the world over must continue to disagree with a policy of inflicting caesarean scars because it suits the practice of the richer nations.

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1 Hannah ME, Hannah WJ, Hewson SA, Hodnett ED, Saigal S, Willan AR, for the Term Breech Trial Collaborative Group. Planned caesarean section versus planned vaginal birth for breech presentation at term: a randomised multicentre trial. Lancet 2000; 356: 1375-83.

Sir—The report by Mary Hannah and colleagues1 gives no information about the number of women eligible to be recruited. In some centres, fewer than 1% of eligible women were recruited.

Randomised trials are generally judged as the gold standard for providing information on clinical issues, but low recruitment rates can lead to substantial bias. For example, an obstetrician might recruit a woman to the trial only if he or she was uncertain about the optimum method of delivery. Uncertainty might lead to an adverse outcome for the child.

register-based In Sweden. а nationwide survey2 has shown a nonsignificant association between term breech presentation and very low intrapartum and early neonatal mortality rates (0.9 per 1000 livebirths for vaginal delivery, 0.5 per 1000 livebirths for caesearan section, relative risk 1.81). The Swedish numbers were not analysed by intention to treat, but the intrapartum and early neonatal mortality rates for vaginal births were much lower than those for countries in the low national perinatal mortality rate group of Hannah and colleagues.

If Hannah and colleagues' results did not arise through recruitment bias, and countries such as the UK cannot match the Swedish numbers, the causes of adverse perinatal outcome with breech presentation must be investigated, especially failure to recognise and treat intrapartum hypoxia.3

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## Syndrome X in testicularcancer survivors

Sir-In their report, Mervi Taskinen and colleagues (Sept 16, p 993); describe impaired glucose tolerance and dyslipidaemia as late effects after transplantation bone-marrow childhood.

Close monitoring of long-term survivors of bone-marrow transplantations showed insulin resistance and prompted the study. Taskinen and colleagues describe a high frequency of the core signs of syndrome X2 in long-term survivors of bone-marrow transplantation. The importance of the findings, as noted in the accompanying Commentary by Gérard Socié,3 is that this syndrome might, in these survivors, increase the risk for cardiovascular disease and affect their quality of life and ultimate outlook. Moreover, several risk factors of this syndrome can be treated if recognised. The frequency of the core signs of syndrome X in the bonemarrow-transplanted survivors was higher than in a small group of leukaemia survivors treated with only However, chemotherapy. leukaemia group was investigated only 3 years after treatment, whereas the median follow-up of the transplanted patients was 10.8 years. This difference in follow-up duration could have altered the outcome of the comparison. Taskinen and colleagues also note that hypogonadism was an important factor associated with insulin resistance. This long-term side-effect related to chemotherapy and radiotherapy might be important in the pathogenesis of syndrome X. However, they do not address the possible effect of different schedules and doses of the administered cytotoxic therapy on the frequency of the syndrome.

survivors long-term Ιn disseminated testicular cancer, we saw that many developed a cardiovascular risk-factor profile similar to that of syndrome X after non-ablative chemotherapy. Five patients were