



## Research Roundup

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### AIMS Journal, Autumn 1999, Vol 11 No 3

- [Anti-Progestins \(Mifepristone\) for Induction?](#)
- [Breech Babies in the Womb](#)
- [Men: Try the Empathy Belly](#)
- [Is There Protein in the Urine?](#)

### Anti Progestins for Induction?

A recent small randomized study in Stockholm compared mifepristone for induction of labour with a placebo.

Mifepristone is an anti-progesterone. Progesterone, a natural hormone, is high during pregnancy, and this drug, from Roussel, has been proved as an effective means of causing abortion by lowering progesterone levels. In this study 24 women got the drug and 12 the placebo. The study reports that it proved "a simple and effective method of inducing labour in post-term women with an unripe cervix." Other studies suggest that by using mifepristone, it might be possible to lower the amount of oxytocin or prostaglandins women need.

The health of the babies is to be studied 1-2 years after delivery. This is not good enough. The drug is known to cross the placenta. Theoretically a drastic fall in the levels of progesterone the baby is exposed to before birth could affect sexual development, sexual orientation or have other effects. We would not know of such effects until the children reached maturity. Our joint charter on Maternity Research with the NCT calls for long-term follow up of unborn children involved in randomised trials, and we think this is a case where it is essential. Unfortunately the sample is a small one and the Ethics Committee has unfortunately accepted a design where the placebo group were only half the size of those who were treated, so getting meaningful results will be difficult.

### AIMS Comment

We are not that keen on animal studies, but since mifepristone has already been used to cause induction in monkeys the very least we could expect is data on what happened to the baby monkeys when they grew up - as well as any long term effects on mothers.

The study included no data on what women in both groups thought of the experience. We now regard

omission of such data - from a properly designed study - as unethical.

We are sending our views to the researchers, the Ethics Committee at the Karolinska Hospital, and the Swedish Medical Research Council who supported the study.

## Reference

- Stenlund P, et al. Induction of labor with mifepristone - a randomized double-blind study versus placebo *Acta Obstet Gynecol Scand*, 1999; 78: 7933-798.

## Breech Babies in the Womb

A recent paper from Nottingham tackles an important subject. Breech births can have poorer outcome than babies presenting head first. Is the fact that they happen to be the wrong way round the only problem - or do breech babies stay that way because they already have other problems?

The researchers wanted to see whether breech presentation meant there was abnormal neuro-development of the fetus. To do so they did prolonged Doppler ultrasound studies plus fetal monitors for at least an hour on 26 babies who were breech at 36 weeks and 58 babies who were cephalic (head down). A previous study from Japan had shown subtle differences in eye movement patterns.

Heart patterns in both groups were the same, but breech babies moved from one behaviour to another more often. However, there could be a number of explanations for this, e.g. although the babies move more often, for some reason they are not capable of the sustained movement which would get them into a head-down position. Or it could be that being in the breech position itself affects behaviour. The authors suggest that studies before and after breech babies are turned by external cephalic version might help to answer the question as to whether the baby's behaviour is the cause or the effect of being in the breech position.

## AIMS Comment

Our regular readers will know what is coming: 84 babies - 58 of them in normal cephalic position - were exposed to at least 60 minutes of Doppler ultrasound (more powerful than real-time scans) for research purposes. What information were women given before they consented? Did it, for example, include the Australian data on reduced fetal growth following brief Doppler exposure? Our view is that full information on possible hazards should be given when women are asked to involve their unborn children in such studies, and also that Ethics Committees should insist on an unexposed control group twice the size of the study group, so that both groups can be followed up to monitor possible long term hazards.

However, the reasons why a baby may be breech is often discussed with us by mothers who are offered external cephalic version. "Maybe my baby has a reason for being that way, and it may not be a good idea to push him another way round". They often see it from the baby's point of view and if fetal positioning exercises don't work, they do not want the baby disturbed.

## Reference

- Kean L, et al. A comparison of fetal behaviour in breech and cephalic presentations at term, Br J Ob Gyn, 1999; 106: 1209-13.

## Men: Try the Empathy Belly

An advertisement in a recent edition of Birth offers the chance to buy an "Empathy Belly" pregnancy simulator and a wonderful opportunity for the wearer to experience over 20 symptoms of pregnancy. They include a weight gain of 33 pounds, fetal kicking, shallow breathing and shortness of breath, increased blood pressure, pulse and temperature, bladder pressure and frequency of urination, shift in centre of gravity and waddling gait, increase in lower backache, and change in sexual self image.....

The manufacturers suggest it as useful tool for childbirth education, and teen pregnancy prevention. We think it might also come in handy for bosses, government ministers and MPs and public transport planners of both sexes.

Alas the manufacturers in the USA do not mention the price, but you can contact them on their website at [www.empathybelly.org](http://www.empathybelly.org) or write to Birthways Box 1069, Vashon, WA 98070-2269 USA.

If anyone tries this, we would like to have your comments!

## Is There Protein in the Urine?

One of the commonest and most important tests carried out on pregnant women is the dipstick test of urine to see if protein is present, since this is part of the important check for pre-eclampsia, a life-threatening condition for mother and baby. A recent study at Leicester looked at how accurately the test was done. Dipstick analysis is done mostly by nursing auxiliaries and midwives. 20 auxiliaries, 20 midwives and 9 lab technicians were asked to score five protein solutions, two of which should have scored negative, and three positive on a dipstick test.

The nursing auxiliaries were more inaccurate than the midwives. 8 out of 20 and 11 out of 20 auxiliaries reported protein in two solutions which should have been negative. The number reported by midwives were 1 and 6 in 20. It was the least experienced midwives who had the highest false positive rates. In the three higher concentration solutions, nursing auxiliaries reported false negatives in 3 out of 60 cases, and midwives 4 out of 60 cases. However in the two highest concentrations there was only one false negative - from a nursing auxiliary.

The authors also asked laboratory staff to do the tests. Before training there were many false positives and a few false negatives. After training there were hardly any false positives and false negatives were equally rare. Training, according to the manufacturers instructions meant that inexperienced lab staff could reach the standard of expert midwives.

Researchers found the commonest problem before training was "rounding up" slight colour changes to put them in the "+1" group.

The authors conclude that dipstick analysis of urine is only moderately reliable, and suggest that all women with prolonged high blood pressure in pregnancy should have a 24-hour analysis of protein in urine.

### **AIMS Comment**

Many's the time we have wondered about the accuracy of the dipstick analysis when women tell us about multiple signs of severe pre-eclampsia with an apparently negative test of protein in urine. Was it really not there, or did the test or the tester not pick it up? One thing is for sure - a negative test does not exclude pre-eclampsia. On the other hand we are suspicious of some of the apparent positive tests which are used to re-route women from home birth to hospital all-too conveniently, even though it turns out nothing is wrong with them. If lab staff can be trained to interpret dipstick results, so can pregnant women, and we would like to see a formal study.

Meanwhile we thank the Leicester team for a useful study, which should be circulated to all Maternity Service Liaison Committees.

### **Reference**

- Bell, S, et al. The role of observer error in antenatal dipstick proteinuria analysis, Br J Ob Gyn, 1999; 106: 1177-80.