A multicentre, randomised controlled trial of position during the late stages of labour in nulliparous women with an epidural: clinical effectiveness and an economic evaluation (BUMPES)

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Scientific summary

The BUMPES RCT

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Scientific summary

Background

As the most effective form of pain relief in labour, epidural analgesia is chosen by up to 30% of women in the UK each year, and this proportion has remained relatively stable since 1990. Epidural analgesia leads to an increased risk of instrumental vaginal delivery (IVD); however, this evidence comes mostly from trials using epidural techniques that caused dense neuraxial blockade. 'Low-dose epidurals', which use low-dose local anaesthetic in combination with opioids, result in a lower risk of IVD; however, using this method, the rate of IVD is still higher than that in women with no epidural. Although low-dose epidurals preserve motor function, allowing greater mobility throughout labour and enabling women to adopt upright positions, there is debate about whether or not an upright posture in the second stage of labour increases the incidence of spontaneous vaginal birth (SVB).

A Cochrane review of position in the second stage of labour in women *without* epidurals showed a reduction in IVD in the upright group (Gupta JK, Hofmeyr GJ, Shehmar M. Position in the second stage of labour for women without epidural anaesthesia. *Cochrane Database Syst Rev* 2012;**5**:CD002006). A Cochrane review of position in the second stage of labour for women with epidural analgesia was published in 2013 (Kemp E, Kingswood CJ, Kibuka M, Thornton JG. Position in the second stage of labour for women with epidural anaesthesia. *Cochrane Database Syst Rev* 2013;**1**:CD008070), after the BUMPES trial was started. This review included trials which compared upright with recumbent positions. The incidence of SVB reported in the five included trials, comprising 879 women in total, was 1.02 [95% confidence interval (CI) 0.81 to 1.28]. The authors concluded that there was no clear evidence about whether or not position in the second stage of labour made a difference to outcomes.

Objectives

To evaluate whether or not, in nulliparous women who choose low-dose epidural analgesia, a policy of adopting an 'upright position' throughout the second stage of labour is associated with an increase in the incidence of SVB compared with a policy of adopting a 'lying-down' position.

Design

A two-arm randomised controlled trial.

Setting

Maternity units in England and Wales.

Participants

Women admitted to a participating labour ward who fulfilled all of the following criteria were eligible to be recruited and randomised into the trial:

- aged ≥ 16 years
- ≥ 37 weeks' gestation

- nulliparous (no previous delivery $\geq 24^{+0}$ weeks' gestation)
- singleton cephalic presentation
- intended SVB
- in the second stage of labour
- with a low-dose epidural in situ during the first stage of labour, providing effective pain relief
- able to understand printed documentation produced in English
- able to give written answers in English.

Exclusion criteria

Women who did not fulfil all of the inclusion criteria were not included in the study.

Interventions

Women were allocated to a policy of (1) an upright maternal position that would maintain the pelvis in as vertical a plane as possible during the second stage of labour, with the intention of continuing this until the birth (this could include walking, standing, sitting out of bed, supported kneeling or completely upright in an obstetric bed for as much of the second stage as possible); or (2) a lying-down maternal position (left or right lateral, to prevent aortocaval compression), which would maintain the pelvis in as horizontal a plane as possible during the second stage of labour, with the intention of continuing this until the birth.

Randomisation

Participants were randomised to the allocated intervention (allocation ratio 1 : 1) using a secure web-based central randomisation service. No stratification by clinical characteristics was undertaken, although there was stratification by centre.

Main outcome measures

Primary outcome measure

The primary outcome measure was the incidence of SVB.

Secondary short-term outcomes

- Instrumental vaginal delivery (forceps and ventouse).
- Caesarean section.
- Augmentation of labour.
- Major interventions to maintain blood pressure (e.g. vasopressors).
- Hypotension (systolic blood pressure of < 100 mmHg prior to delivery).
- Application of fetal scalp electrode.
- Fetal blood sampling.
- Total doses of epidural local anaesthetic and opioids administered after randomisation.
- Duration of active second stage of labour.
- Total duration of second stage of labour.
- Additional anaesthesia used for operative delivery.
- Active management of the third stage of labour.
- Episiotomy.
- Pain during delivery.
- Genital tract trauma (location and severity).
- Manual removal of the placenta.
- Primary post-partum haemorrhage necessitating blood transfusion.

- Duration of maternal inpatient stay after delivery.
- Satisfaction with experience of birth.
- Cord artery pH of < 7.05 in the second stage of labour (this is 2 standard deviations below the mean) with base deficit of ≥ 12 mmol/l (this is the threshold above which the risks of neurological damage increase).
- Presence of meconium-stained liquor.
- Apgar score of < 4 at 5 minutes.
- Resuscitation at birth.
- Skin-to-skin contact within the first hour of birth.
- Initiation of breastfeeding within the first hour of birth.
- Duration of infant inpatient stay.
- Admission to neonatal unit and duration of stay.

At 1 year

- Urinary incontinence.
- Faecal incontinence.
- Other bowel problems.
- Dyspareunia.
- General physical and psychological health.
- Major infant morbidity, for example gross neurodevelopmental delay, including cerebral palsy (if a diagnosis has been made).
- Hospital admissions.

Economic evaluation

A cost–consequences analysis with a time horizon of a 1-year follow-up and a NHS perspective was conducted alongside BUMPES.

Data collection schedule

Information at trial entry was collected from hospital notes and entered onto specifically designed study data collection booklets. The attending midwife recorded data about what position the woman was in during the second stage of labour 'for the majority of the time in the last 15 minutes', if this position had changed from the allocated position and the reasons for this. We collected clinical outcome information on the birth as well as neonatal outcomes and hospital inpatient stay data. As soon as possible after the birth, the woman was asked to complete a one-page questionnaire asking about her satisfaction with her birth experience. Women with surviving infants were followed up at 1 year with a self-administered questionnaire asking about specific health problems, their general health, the well-being of their infant's health and their use of NHS health-care resources.

Sample size and analysis

Assuming a rate for the primary outcome of SVB of 55% in the control group [derived from data published from the Comparative Obstetric Mobile Epidural Trial (COMET), which was a randomised trial that compared conventional epidural analgesia with low-dose epidural analgesia in nulliparous women in labour], a sample size of 3000 women (1500 in each arm) would have 90% power to detect a clinically significant (absolute) difference of 6% in the SVB rate between the two policies (with 95% CIs).

A detailed statistical analysis plan was developed and approved by the Trial Steering Committee prior to analysis of the trial data. For the primary analysis, participants were analysed in the groups into which they were randomly allocated, regardless of position recorded at any time during the second stage of labour. In order to take account of the number of comparisons, 95% CIs are presented for the primary outcome and 99% CIs for all other outcomes.

To examine whether or not the effect of the policy of position during the second stage of labour was consistent across specific subgroups, the following prespecified subgroup analyses were undertaken:

- gestational age (37^{+0} to 38^{+6} weeks; 39^{+0} to 40^{+6} weeks; and $\geq 41^{+0}$ weeks)
- maternal age ($\leq$ 24 years, 25–29 years, 30–34 years and $\geq$ 35 years)
- augmentation with oxytocin (Syntocinon®; Novartis Pharmaceuticals UK Ltd, Frimley/Camberley, UK) in the first stage of labour (yes/no)
- Index of Multiple Deprivation (population-based quintiles 1–5).

Results

Between October 2010 and January 2014, 3236 women were randomised to the BUMPES trial from 41 participating centres in England and Wales.

A total of 143 women (4.4%) were excluded from the analysis of the primary outcome. Data collection booklets were available for 100% of women recruited and analysed. Follow-up at 1 year was achieved for 61% of women.

Baseline characteristics were similar between the two arms of the trial.

There was a clear difference in the incidence of the primary outcome, SVB, between the groups, with 35.2% of women achieving SVB in the upright group, compared with 41.1% in the lying-down group (adjusted relative risk 0.86, 95% CI 0.78 to 0.94). This represents a 5.9% absolute risk increase in the chance of SVB in the lying-down group.

There was no evidence of a difference in most of the secondary maternal outcomes after study entry and during the second stage of labour. There was a significant difference in the duration of the active second stage of labour, which was shorter in the lying-down group (geometric mean ratio 1.08 minutes, 99% CI 1.01 to 1.15 minutes). Other secondary maternal outcomes, such as IVD and caesarean section, suggested an increased risk associated with the upright position, but these differences were not statistically significant at the 1% level. For example, the incidence of episiotomy was higher in the upright group than in the lying-down group (although the difference was not significant at the 1% level). There were no statistically significant differences in the risk of perineal trauma, although there appeared to be a slightly higher incidence of obstetric anal sphincter injury in the upright group (6.7%) than in the lying-down group (5.3%), but again this difference was not statistically significant at the 1% level.

Maternal satisfaction in labour was similar between the two groups.

Infant outcomes were extremely good throughout, with very few babies having a low Apgar score at 5 minutes or evidence of metabolic acidosis. Overall, about 12% of babies required resuscitation at birth.

The prespecified subgroup analyses showed no evidence of heterogeneity between any of the prespecified subgroups for the primary outcome of SVB.

There was no evidence of any differences between the groups in relation to the incidence or severity of urinary incontinence, faecal incontinence, constipation, haemorrhoids or dyspareunia, or general

well-being. Similarly, there was no evidence of a difference in the incidence of diagnosed cerebral palsy or severe neurodevelopmental delay in any of the infants at 1 year.

Cost-effectiveness analysis

Women randomised to the lying-down position consumed significantly fewer NHS resources than those randomised to an upright position during the original hospital stay [mean cost difference of £59 (95% CI £6 to £111) favouring the lying-down position]. This result was driven by more SVBs in the lying-down arm. At the 12-month follow-up, there were no significant differences in the overall costs incurred by mothers or their babies between the upright and lying-down groups. The significantly higher costs incurred by the women in the upright group were offset by the slightly, but non-significantly, higher costs incurred during follow-up by the women in the lying-down group.

Conclusions

There is clear evidence of a benefit of adopting a lying-down (lateral) position in the second stage of labour in nulliparous women with epidural analgesia, with no apparent disadvantages in relation to either short- or long-term outcomes for either mother or baby, and this is cost neutral for the NHS.

Like all pragmatic trials, the study had limitations. With an intervention such as this, masking is impossible, so the results may have been influenced by the women's and the midwives' perceptions of the different positions in their ability to achieve a SVB. Given that existing National Institute for Health and Care Excellence guidance recommends that women with an epidural should be encouraged to adopt whatever upright position they find comfortable, we might expect the trial results to suggest an improvement in SVB with an upright position if midwives' and women's behaviour was altered in these positions because of a firm belief that these were preferable. The findings that the lying-down position increased the chances of achieving a SVB suggest that this potential bias was either absent or minimal in its impact, or that the likelihood of the lying-down position leading to a SVB may be even greater.

We can only speculate about the mechanism by which a lying-down position increases the chance of a SVB. We have no direct measurements of the density of the epidural block in the two positions or of the level of the block. It is possible that women in the upright position acquired a more dense block around the birth canal because of the effect of gravity on the epidural drugs, which could have made expulsive efforts more difficult; however, the similarity of drug doses used in each group would suggest that this is unlikely. Women in the upright group, who may have been sitting, may have restricted the pelvic outlet because of the position on the coccyx or because of lower genital tract oedema and venous obstruction causing swelling of the soft tissues obstructing the pelvic outlet. In addition, it is possible that, in the lying-down group, easing of pressure of the fetal head on the pelvis improved uterine blood flow and therefore improved uterine activity. This would suggest a difference in the risk of operative delivery associated with failure to progress; however, the distribution of indications for operative delivery appeared to be the same in both groups. In addition, there was little difference in the use of oxytocin because of delay in labour progress after trial entry.

The response rate to the 1-year follow-up was 61%. Therefore, there is a possibility that the follow-up results are less than robust because of non-response bias. There were, however, no apparent differences in the response rates or characteristics of the two randomised groups, suggesting that there were minimal biases in the comparison of the two groups.

The lack of an impact of the risk of SVB on longer-term outcomes such as faecal incontinence is of interest. The observation that IVD is associated with increased risks of faecal incontinence is robust; however, in the BUMPES trial, the differences between the randomised groups of women in their risk of

SVB and IVD were relatively small, so, although there are associations between different modes of birth and long-term outcomes, these are likely to be diluted in a trial in which the differences in actual mode of birth are relatively modest (a 6% absolute difference in the risk of SVB). This is likely to explain the lack of an observed difference in long-term outcomes.

Trial registration

This trial is registered as ISRCTN35706297.

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