Urinary catheterization in labour with high-dose vs mobile epidural analgesia: a randomized controlled trial

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Background. Dense perineal block from epidural analgesia increases the risk of urinary catheterization in labour. Mobile epidurals using low-dose local anaesthetic in combination with opioid preserve maternal mobility and may reduce the risk of bladder dysfunction. We conducted a three-arm randomized controlled trial to compare high-dose epidural pain relief with two mobile epidural techniques.

Methods. A total of 1054 primiparous women were randomized to receive high-dose bupivacaine, epidural analgesia (Control), combined spinal epidural (CSE), or low-dose infusion (LDI). The requirement for urinary catheterization during labour and postpartum was recorded. Both end points were pre-specified secondary trial outcomes. Women were evaluated by postnatal interview, when their bladder function had returned to normal.

Results. Relative to Control, more women who received mobile epidural techniques maintained the ability to void urine spontaneously at any time (Control 11%, CSE 31% and LDI 32%) and throughout labour (Control 3.7%, CSE 13% and LDI 14%), for both mobile techniques \( P < 0.01 \). There was no difference in the requirement for catheterization after delivery. Women in the CSE group reported a more rapid return of normal voiding sensation, relative to high-dose Control \( (P=0.02) \).

Conclusions. Relative to conventional high-dose block, mobile epidural techniques encourage the retention of normal bladder function and reduce the risk of urinary catheterization in labour.


Keywords: anaesthetic techniques, epidural; labour

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Continuous epidural analgesia is the most effective method of pain relief during childbirth.¹ More than 150 000 women use epidural analgesia for labour and delivery every year in the UK and Wales,² approximately one-fifth of the parturient population.³ The efficacy of epidural analgesia comes at the cost of important side-effects including an increased rate of instrumental vaginal delivery, prolonged duration of labour (notably second stage) and increased augmentation with oxytocin.

Many of these deleterious effects may be linked to the motor and sensory block that accompany epidural pain relief using ‘concentrated’ local anaesthetic solutions [i.e. bupivacaine 0.25% (2.5 mg ml⁻¹) or greater]. In response to this possible causal relationship, ‘low-dose’ or ‘mobile’ epidural techniques were developed, using dilute concentrations of local anaesthetic solutions (bupivacaine 0.125% or less) in combination with epidural opioids (fentanyl), with the aim of delivering effective pain relief while allowing retention of maternal perineal sensation and lower limb mobility.

Relative to high-dose regimens, mobile epidurals increase maternal satisfaction.⁴ Furthermore, the Comparative Obstetric Mobile Epidural Trial (COMET) demonstrated a reduction in instrumental vaginal delivery rate with
combined spinal epidural (CSE) and low-dose infusion (LDI) techniques and an improvement in the progress of labour.5

The effect of epidural analgesia on bladder function during and after childbirth remains under-investigated. Dense epidural block may result in absent bladder sensation and an associated risk of intrapartum urinary retention and over-distension injury if this goes unrecognized. Epidural analgesia has been identified as an independent risk factor for postpartum urinary retention,6 however, few studies have sought to distinguish between the effects of different epidural techniques, examining only whether an epidural was used or not. Here, we report the effect of epidural technique on the requirement for urinary instrumentation during and after labour, examined as a secondary outcome of COMET.

Methods

The study population included all nulliparous women who requested epidural pain relief for labour at Birmingham Women’s Hospital and Leicester Royal Infirmary, UK, recruited to COMET over a period of 15 months. Women were not eligible if they had a contraindication to epidural analgesia, had undergone a previous epidural or spinal procedure, or had received systemic opioids [meperidine (pethidine)] for pain relief in the preceding 4 h. All nulliparous women included in this study were given information by the trial centres about the study at 34 weeks gestation. On request for epidural pain relief, further information was imparted by the duty anaesthetist and written consent was obtained. Ethics committees at both centres approved the study.

Women were allocated randomly to one of the three epidural techniques, balanced according to age and ethnic group using minimization. This was done through a customized computer randomization programme located on the labour ward, by the consenting duty anaesthetist. For all epidural techniques, women received an i.v. volume pre-load of 500 ml Hartmann’s solution. Epidurals were sited under aseptic conditions, with a 16-gauge Tuohy needle (Sims, Portex Ltd, Hythe, UK) in a suitable lumbar interspace, in the sitting or lateral position, with a midline approach. Loss of resistance to air or saline was used for identification of the epidural space, according to operator preference. Both mobile techniques used a sterile ‘low-dose mixture’ of bupivacaine 0.1% (1 mg ml⁻¹) with fentanyl 2 µg ml⁻¹ pre-mixed by a commercial pharmacy.

Control group

After epidural insertion, a test dose of 3 ml lignocaine 2% (60 mg) was administered, to exclude intrathecal placement of the epidural catheter. Analgesia was initiated with 10 ml bupivacaine 0.25% (25 mg) 5 min after confirmation of a negative test dose. Subsequent doses of 10 ml bupivacaine 0.25% (25 mg) were administered by midwifery staff, provided on maternal request for pain relief, but no more than hourly.

Combined spinal epidural

Analgesia was established by subarachnoid injection, through a 120-mm, 24-gauge Standard Sprotte®, pencil point, atraumatic needle (Pajunk, Medizintechnologie, Geisingen, Germany), with 1 ml bupivacaine 0.25% (2.5 mg) and 25 µg fentanyl (total volume 1.5 ml) using a needle-through-needle method at a single spinal interspace. As spinal analgesia wore off, epidural block was established by administration of 15 ml of low-dose mixture (bupivacaine 15 mg, fentanyl 30 µg) through the epidural catheter. Subsequent analgesia was given intermittently by bolus of 10 ml low-dose mixture, on maternal request, but no more frequently than every 30 min. To minimize the risk of Post Dural Puncture Headache from the spinal element of the technique, only one attempt at intrathecal injection was permitted in the CSE protocol. If this failed to obtain a verified subarachnoid placement of the needle, with identifiable cerebrospinal fluid, epidural block was initiated immediately with 15 ml of low-dose mixture (bupivacaine 15 mg, fentanyl 30 µg).

Low-dose infusion

Analgesia was established with an epidural injection of 15 ml of low-dose mixture (bupivacaine 15 mg, fentanyl 30 µg). A fixed rate infusion of low-dose mixture at 10 ml h⁻¹ was commenced immediately thereafter, through a portable Baxter AP2 Pump® (Deerfield, USA), containing 100 ml of the solution. The rate of epidural infusion did not alter throughout labour. To treat inadequate pain relief, despite continuous infusion, doses of 10 ml of low-dose mixture were given, on maternal request, but no more than hourly. The infusion was interrupted only briefly to administer these manual top-ups and re-started immediately thereafter. The infusion was discontinued at the end of the third stage of labour, or at instrumental/operative intervention for delivery.

No epidural local anaesthetic was given in either mobile technique before administering the bolus of low-dose mixture to initiate epidural pain relief. Relative to the doses of local anaesthetic given to establish epidural analgesia (bupivacaine 15 mg), a test dose of lignocaine 60 mg would have a significant peripheral motor effect.

Inadequate pain relief in the Control group, despite hourly top-ups, was treated by administration of epidural fentanyl 50 µg, diluted to a total volume of 5 ml, with sterile saline 0.9%, more concentrated bupivacaine solutions (5–10 ml bupivacaine 0.375% or 0.5%) or both. Initial rescue analgesia in each of the CSE and LDI groups comprised a further 10 ml bolus of the low-dose mixture, administered by anaesthetic staff. If inadequate analgesia...
Sample size
Sample size calculations were made for the primary short- and long-term outcome measures. Power calculations for the primary short-term outcome, mode of delivery, were based on a retrospective analysis of a standardized group of nulliparous women at Queen Charlotte’s Hospital, London, where CSE was first introduced as a routine procedure. It was calculated that a change in spontaneous vaginal delivery from 50 to 65% with a power of 80% (1-beta) and 5% significance level (two-sided alpha) would require 180 women in each arm.

The recruitment of a greater number of women in each arm of the trial was dictated by the lower prevalence of backache, the primary long-term outcome of COMET. Sample size calculations for this outcome were based on long-term back ache rates in earlier studies by members of the COMET study group (18.9% compared with 10.5%). To identify a reduction of this order with a 5% Type 1 error and 80% power, a sample size of 314 was required in each group. Taking into account the anticipated losses to 12 month postpartum questionnaires, it was decided to recruit 350 women to each arm of the trial.

The results presented here represent an analysis of pre-specified short-term secondary outcomes. Although sample size calculations were not undertaken for secondary outcomes, it was considered that a sample size of 1050 would detect any clinically important differences in bladder function between trial groups.

Statistical analysis
Statistical analysis was conducted with SPSS for Windows version 10 (© SPSS UK Ltd, Woking, Surrey, UK) using χ² tests for discrete variables. The small number of women who delivered before an epidural could be sited or received a technique different from their randomized allocation (see Fig. 1) was analysed in the trial arm to which they had been originally allocated (‘intention-to-treat’). All comparisons were between each mobile technique relative to Control, not between mobile groups. Significance levels for pre-specified outcomes were set at P<0.05.

Results
Of the 1054 nulliparous women recruited, 353 were randomly allocated to Control, 351 to CSE, and 350 to LDI. This represented a 55% recruitment rate (24 h day⁻¹) from eligible women. Figure 1 shows the progress of all eligible women through the study. The most common reason for non-recruitment was not being asked to take part in the study, as a result of clinical workload. The baseline characteristics and birth weights are given in Table 1, showing that these were similar across trial groups. Delivery mode, the primary short-term trial outcome, is also shown.

Intrapartum bladder function
Table 2 displays the requirement for urinary catheterization during labour, for women in each epidural group. Relative to the Control group, both CSE and LDI had a significant reduction in the requirement for intermittent urinary catheterization during labour and an increase in the ability of women to void urine spontaneously, even if urinary catheterization was eventually required at some point before delivery. The number of women who had an indwelling urinary catheter sited in labour was small and similar between the trial groups.
**Postpartum bladder function**

By the time of postpartum interview, usually the day after delivery, the majority of women said they had been able to void spontaneously and this did not differ between the trial groups (Table 3). However, voiding sensation was more likely to have returned within 6 h of delivery, in the CSE group relative to the Control group ($P=0.02$). No differences in the return of voiding sensation were found between LDI and Control. There were no differences in the number of women who required catheterization after delivery between groups or in the reported prevalence of urinary incontinence, which was small, overall. Women
The prevalence and aetiology of persistent postpartum urinary retention. A prospective evaluation of vaginal delivery, required medio-lateral episiotomy and more likely to be nulliparous, undergone instrumental vaginal delivery, required medio-lateral episiotomy and received regional analgesia. A prospective evaluation of the prevalence and aetiology of persistent postpartum urinary retention in 8402 consecutive, unselected deliveries was conducted at a university maternity hospital. Women unable to void after the third postnatal day, despite intermittent catheterization, were diagnosed to be in persistent postpartum urinary retention. These patients were more likely to have delivered vaginally after a previous Caesarean section, received epidural analgesia for pain relief and had prolonged second-stage labour.

Postpartum bladder surveillance by ultrasonography is a routine investigation in the diagnosis of urinary retention. A prospective trial compared 110 nulliparous women, who had delivered vaginally, with epidural analgesia and a matched comparison group of 100 women without epidural analgesia. Residual urine volumes were estimated by trans-abdominal sonogram. Women who had received epidural analgesia, diagnosed with postpartum urinary retention (residual volume exceeding 500 ml), were found to have undergone significantly longer labours and had more perineal lacerations than women in the non-epidural comparison group. The authors concluded that postpartum urinary retention was related to prolonged labour rather than epidural analgesia per se.

Few studies have specifically set out to elucidate the effect of epidural technique on the incidence of postpartum urinary retention. A trial by Olofsson and colleagues randomized 1000 women to either bupivacaine 0.25% with adrenaline 1:200 000 or bupivacaine 0.125% with sufentanil 10 μg for epidural analgesia during labour. During the same period, all women delivering with or without epidural were observed for the development of clinically significant postpartum urinary retention. The overall incidence of retention was low (0.9%); however, nearly all patients diagnosed with retention (27/30) had received epidural pain relief. The incidence of retention in the two epidural techniques was similar and in patients with retention, who had received epidural, the incidence of instrumental delivery or perineal tears was the same between the groups. The authors concluded that epidural analgesia significantly increased the risk of postpartum urinary retention.

The findings in our trial have shown that mobile epidurals reduce urinary catheterization during labour. A historical control study of the impact of the introduction of mobile epidurals into practice produced data in support of this. In an examination of 150 deliveries before and 150 after the introduction of a mobile epidural technique into practice, a significant reduction in the requirement for urinary catheterization in labour was noted (32 vs 7%).

There are limitations to our trial. The distinctions between epidural techniques made it impractical to blind women (or their attendant midwives) to their study group allocation. Thus, it could be argued that women’s expectations of a particular technique may have influenced their reports of return of normal bladder function. The trial was not resourced to undertake ultrasonic examination of each woman for evidence of urinary retention.

### Table 2 Intrapartum bladder function by trial group. *P*<0.01

<table>
<thead>
<tr>
<th>Trial Group</th>
<th>Control (n=353)</th>
<th>CSE (n=351)</th>
<th>LDI (n=350)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voided spontaneously (any time during labour) [n (%)]</td>
<td>38 (11)</td>
<td>107* (31)</td>
<td>111* (32)</td>
</tr>
<tr>
<td>Voided spontaneously (throughout labour) [n (%)]</td>
<td>13 (3.7)</td>
<td>46* (13)</td>
<td>48* (14)</td>
</tr>
<tr>
<td>Required intermittent catheterization [n (%)]</td>
<td>278 (79)</td>
<td>239 (68)</td>
<td>218 (62)</td>
</tr>
<tr>
<td>Required indwelling catheter</td>
<td>4</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>Missing</td>
<td>56</td>
<td>81</td>
<td>60</td>
</tr>
</tbody>
</table>

### Table 3 Postpartum bladder function by trial group. *P*<0.02

<table>
<thead>
<tr>
<th>Postpartum outcome</th>
<th>Control (n=349)</th>
<th>CSE (n=348)</th>
<th>LDI (n=344)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Already voided spontaneously</td>
<td>243 (69.6)</td>
<td>253 (72.7)</td>
<td>250 (72.7)</td>
</tr>
<tr>
<td>Voiding sensation returned within ≤6 h</td>
<td>141 (40.4)</td>
<td>172 (49.4)</td>
<td>139 (40.4)</td>
</tr>
<tr>
<td>&gt;6 h</td>
<td>92 (26.6)</td>
<td>70* (20.2)</td>
<td>95 (27.6)</td>
</tr>
<tr>
<td>Postpartum urinary catheter</td>
<td>119 (34.1)</td>
<td>108 (31.0)</td>
<td>113 (32.8)</td>
</tr>
<tr>
<td>Intermittent</td>
<td>32 (9.2)</td>
<td>37 (10.6)</td>
<td>24 (7.0)</td>
</tr>
<tr>
<td>Indwelling</td>
<td>87 (24.9)</td>
<td>72 (20.7)</td>
<td>89 (25.9)</td>
</tr>
<tr>
<td>Urinary incontinence</td>
<td>23 (6.6)</td>
<td>23 (6.6)</td>
<td>16 (4.7)</td>
</tr>
</tbody>
</table>

who delivered by Caesarean section uniformly had an indwelling catheter sited at the time of operation, to avoid bladder damage and measure urine output in the postoperative period.

### Discussion

The data from this randomized controlled trial shows that the type of epidural technique used to provide pain relief in labour exerts an important influence on intrapartum urinary function. Women allocated to receive a mobile epidural technique were more likely to retain the ability to void spontaneously during labour and avoid urinary catheterization completely, compared with those in the control group who received high-dose epidurals.

Most investigations into urinary retention that may accompany labour and delivery have concentrated solely on postpartum bladder function, specifically postpartum urinary retention. Studies to determine the incidence of clinically overt postpartum urinary retention have confined themselves to populations of women who delivered vaginally, since patients undergoing Caesarean section are uniformly managed with an indwelling urinary catheter inserted at the time of operation. In a retrospective case–control study, 0.45% of vaginal deliveries were complicated by urinary retention. Women with retention were more likely to be nulliparous, underwent instrumental vaginal delivery, required medio-lateral episiotomy and received regional analgesia. A prospective evaluation of the prevalence and aetiology of persistent postpartum urinary retention.
Instrumental vaginal delivery was less likely in mobile groups. This could affect catheterization rates because it is routine before an assisted delivery. We reported voiding function in two ways, by identifying those women who voided spontaneously ‘at any time’ during labour (even if they required catheterization eventually) and those who avoided catheterization entirely. This distinction was designed to prevent interpretation of an effect of assisted delivery as a difference in bladder function. The differences in catheterization between groups (at ‘any time’ and ‘throughout labour’) were far greater in magnitude than the proportional differences in delivery mode. This reassures us that we have demonstrated a genuine effect, rather than an associated phenomenon.

Whether a reduced incidence of catheterization in labour conveys an advantage into the postpartum period is uncertain. Evidence has recently emerged of an association between bacteruria after delivery and certain risk factors including repeated digital vaginal examinations, vacuum delivery, recurrent bladder catheterization in labour, and the duration of epidural analgesia.12 In those women who delivered vaginally, similar numbers, in each epidural group required urinary catheterization after delivery, for urinary retention. This difference between the peri- and postpartum periods may reflect factors other than the motor and sensory block associated with epidural analgesia, becoming more important in determining urinary function, as analgesia wears off and sensation in the perineum returns to pre-block levels. The earlier return of normal bladder sensation in the CSE group is consistent with the lower dose of local anaesthetic used in this technique.13 Roughly half the dose of bupivacaine was administered in first and second stages of labour in the CSE group [mean 47.7 (SD 38.1) µg] when compared with the Control and LDI groups [means 91.2 (51.3) and 84.9 (52.5) µg, respectively]. It may be that the reduced motor block and increased mobility afforded by the CSE technique assisted in the rapid return of normal bladder sensation and function.

Conclusions
We have demonstrated that mobile epidural analgesia reduces the risk of urinary catheterization in labour, relative to higher dose techniques. Whether this reduction confers advantage in the incidence of postpartum urinary retention, or associated long-term symptoms of urinary incontinence, remains unclear. However, low-dose epidural techniques, which result in reduced instrumental delivery, also result in a greater likelihood of maintenance of normal physiological bladder function during childbirth.

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Appendix: COMET study group

Contributions
The trial was initiated and co-ordinated by C. MacArthur and A. Shennan (principal investigators) who obtained funding together with D. Bick, G. Cooper, M. Lewis and A. May (joint applicants). The trial anaesthetic techniques and protocols were developed by research anaesthetists J. Whyte, M. J. Wilson, and N. Hickman. L. Crewe and M. Patterson (research midwives), together with the research anaesthetists, were responsible for ensuring recruitment, data collection and entry, and training duty anaesthetists and midwives. W. Hussain assisted with recruitment in COMET 1. P. Squire was an additional research midwife for COMET 2, and additional research anaesthetists were S. Bharmal, H. Garston and P. Moore, who had similar responsibilities as the above research staff. L. Gold addressed health economic issues. R. Lancashire and C. MacArthur performed the main outcome analysis, and M. J. Wilson undertook additional analyses into anaesthetic characteristics. M.J. Wilson undertook analyses and drafted the present paper and C. MacArthur and A. Shennan contributed to interpretation of results and production of the final paper. All trial contributors approved the final paper.

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