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Randomized Controlled Trial Comparing Traditional with Two "Mobile" Epidural Techniques

Anesthetic and Analgesic Efficacy

*Comparative Obstetric Mobile Epidural Trial (COMET) Study Group UK**

Background: **The authors recently showed that "mobile" epidural analgesia, using low-dose local anesthetic–opioid mixtures, reduces the impact of epidural analgesia on instrumental vaginal delivery, relative to a traditional technique. The main prespecified assessment of pain relief efficacy, women's postpartum estimates of labor pain after epidural insertion, did not differ. The detailed analgesic efficacy and the anesthetic characteristics of the techniques are reported here.**

Methods: **A total of 1,054 nulliparous women were randomized, in labor, to receive boluses of 10 ml 0.25% bupivacaine (traditional), combined spinal–epidural (CSE) analgesia, or low-dose infusion (LDI), the latter groups utilizing 0.1% bupivacaine with 2 μg/ml fentanyl. Visual analog scale pain assessments were collected throughout labor and delivery and 24 h later. Details of the conduct of epidural analgesia, drug utilization, and requirement for anesthesiologist reattendance were recorded.**

Results: **A total of 353 women were randomized to receive traditional epidural analgesia, 351 received CSE, and 350 received LDI. CSE was associated with a more rapid onset of analgesia, lower median visual analog scale pain scores than traditional in the first hour after epidural insertion, and a significant reduction in bupivacaine dose given during labor. Pain scores reported by women receiving LDI were similar to those in the traditional group throughout labor and delivery. Anesthesiologist reattendance was low but greater with each mobile technique.**

Conclusions: **Relative to traditional epidural analgesia, LDI is at least as effective and CSE provided better pain relief in the early stages after insertion. The proven efficacy of mobile epidurals and their beneficial impact on delivery mode make them the preferred techniques for epidural pain relief in labor.**

RELATIVE to other forms of pain relief for labor, epidural analgesia is the most effective but results in increased rates of instrumental vaginal delivery, prolonged labor, and oxytocin augmentation.[1] Newer epidural techniques, using combinations of opioids with less concentrated local anesthetic solutions, preserve maternal motor function and have been associated with increased maternal satisfaction.[2,3] Nageotte *et al.*[4] showed a reduction in the instrumental vaginal delivery rate with combined spinal–epidural (CSE) analgesia, and we recently demonstrated a reduced instrumental vaginal delivery rate with CSE and a low-dose infusion (LDI) technique in nulliparous women.[5] The spontaneous vaginal delivery rate in women who received a traditional epidural was 35.1% compared with 42.7% in those who received CSE and 42.9% for those who received LDI. The main prespecified assessment of labor pain efficacy did not differ between techniques. It has therefore been suggested[6] that anesthesiologists should offer a regional analgesic technique that interferes least with the normal mechanisms of labor and gives the best chance of a spontaneous delivery, namely, either low-dose CSE or LDI. The latter two techniques are referred to in the text collectively as "mobile epidurals," although this does not necessarily imply maternal ambulation.

Given that mobile epidurals have not yet been uniformly adopted into obstetric anesthetic practice in the United States or United Kingdom[7,8] and that a reduction in instrumental delivery rate represents a compelling reason to abandon traditional epidural techniques,[5] we report in detail the anesthetic and analgesic efficacy of these techniques within our trial population. Since the two comparable maternity units recruiting to the trial (Birmingham Women's Hospital, Birmingham United Kingdom, and Leicester Royal Infirmary, Leicester, United Kingdom, Departments of Anesthesiology) did not previously use mobile epidurals, the findings are likely to reflect the introduction of such techniques into routine labor ward practice.

Materials and Methods

The population included in this study was all nulliparous women requesting epidural for pain relief in labor in two maternity units between August 1997 and April 2000. Exclusion criteria were contraindication to epidural analgesia, previous epidural or spinal analgesia, imminent delivery, or meperidine administration within the previous 4 h (because of the risk of maternal respiratory depression associated with the combined use of intrathecal and systemic opioids). All nulliparous women booked at the two units were sent a study information leaflet at 34 weeks' gestation. Further information was given at the time of request for epidural pain relief, and

* Members of the COMET Study Group UK are listed in the Appendix.

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written consent was obtained by the duty anesthesiologist. The study was approved by local research ethics committees.

Epidural Techniques

In each group, intravenous access was established with a wide bore cannula, and a preload of 500 ml Hartmann's solution was administered. Epidurals were sited with a 16-gauge Tuohy needle (Epidural Minipack; SIMS Portex Ltd., Kent, United Kingdom) in a suitable lumbar interspace, with the patient in the sitting or lateral position, using a midline approach, with loss-of-resistance technique according to operator preference. For the traditional technique, following a test dose of 3 ml lidocaine 2% (60 mg) to exclude intrathecal or intravenous placement of the epidural catheter, analgesia was initiated with 10 ml bupivacaine 0.25% (25 mg) after 5 min. Subsequent boluses of 10 ml bupivacaine 0.25% (25 mg) were provided on request but no more than hourly.

Both mobile techniques used a low-dose mixture of 0.1% bupivacaine with 2 μg/ml fentanyl premixed by a commercial pharmacy under sterile conditions and stored in a locked cupboard on the labor ward as a controlled substance. For the CSE technique, analgesia was established by an intrathecal injection, *via* a 24-gauge Standard Sprotte® needle (Pajunk, Medizintechnologie, Geisingen, Germany), of 1 ml bupivacaine 0.25% and 25 μg fentanyl (total volume, 1.5 ml) using a needle-through-needle method. With the return of painful contractions, as the spinal analgesia wore off, 15 ml of low-dose mixture (15 mg bupivacaine, 30 μg fentanyl) was administered *via* the epidural catheter by the duty anesthesiologist. Subsequent 10-ml boluses of low-dose mixture were given by midwifery staff on maternal request, but no more frequently than half hourly. Only one attempt at intrathecal injection was permitted; if this failed, epidural block was established immediately with 15 ml of low-dose mixture (15 mg bupivacaine, 30 μg fentanyl). For the LDI technique, analgesia was established with an epidural injection of 15 ml of low-dose mixture (15 mg bupivacaine, 30 μg fentanyl). A fixed-rate infusion of low-dose mixture at 10 ml/h was commenced immediately after the first dose *via* a portable Baxter AP2 pump (Baxter Healthcare Corporation, Deerfield, IL). Subsequent top-ups of 10 ml low-dose mixture, in addition to the continuous infusion, were given by midwifery staff on maternal request, but no more frequently than hourly. No epidural test dose was given prior to the first epidural top-up in patients receiving CSE or LDI, to avoid motor blockade.

Inadequate or ineffective pain relief during labor was assessed by the attending anesthesiologist by determination of epidural block height bilaterally to cold spray or light touch. Missed segment or unilateral blockade was treated with lateral patient positioning during epidural top-up. Technical failure of epidural block was treated by resiting the epidural as appropriate. Inadequate pain relief in the traditional group, despite hourly top-ups, was treated with 50 μg epidural fentanyl or more concentrated bupivacaine solutions (5–10 ml bupivacaine 0.375% or 0.5%). Initial "rescue" in each of the CSE and LDI groups comprised a further 10-ml bolus of low-dose mixture, administered by anesthesiology staff. If inadequate analgesia persisted, 5–10 ml 0.25% bupivacaine was administered. Subsequent analgesia for women randomized to the CSE or LDI groups, after rescue, was given according to the original group protocol to which women had been assigned.

For operative deliveries, appropriate doses of local anesthetic were administered to achieve a block sufficient for intervention. In all groups, top-up frequency and infusion rates were continued in the second stage of labor to achieve adequate analgesia.

Women assessed their pain by visual analog score (VAS) on a continuous 100-mm scale (0 being "no pain at all" and 100 "worst pain imaginable"). These scores were recorded before epidural insertion and at 5-min intervals until 30 min after local anesthetic was administered either epidurally or intrathecally. Thereafter, VAS was recorded at hourly intervals through labor. In the absence of operative or instrumental delivery, a VAS of the pain experienced at delivery was recorded. At a postpartum interview approximately 24 h after delivery, a trial midwife recorded further VAS from the women of how painful labor was after epidural insertion (the prespecified main trial assessment of analgesic efficacy) and how painful the birth (delivery) was.

Pain relief was assessed by the attending anesthesiologist at 30 min after insertion as being satisfactory or not. Women were asked to assess pain and perineal sensation at vaginal delivery as "comfortable with sensation," "comfortable without sensation," or "painful."

As one indicator of the workload for anesthesiologists associated with each technique, a record was made, each hour after epidural insertion, of the requirement for reattendance of an anesthesiologist, requested by the attending midwife, for any problem other than routine top-up.

Sample Size, Recruitment, and Randomization

The COMET trial was powered to examine short- and long-term outcomes. The primary predefined short-term outcome was mode of delivery. Power calculations for mode of delivery were based on data from the Department of Anesthesiology at Queen Charlotte's Hospital (London, United Kingdom), where CSE was first introduced as a routine procedure. We calculated that a change in normal vaginal delivery from 50% to 65% with a power of 80% ($1 - \beta$) and 5% significance level (two-sided α) would require 180 women in each arm. The recruitment of 350 women in each arm of the trial was

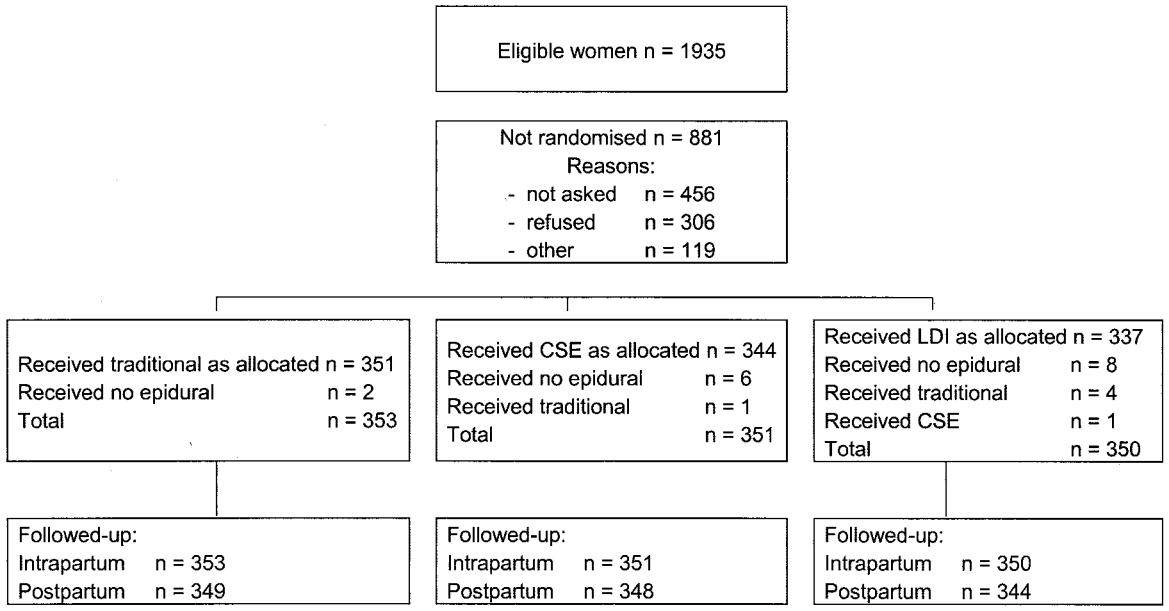

Fig. 1. Progress of women through the Comparative Obstetric Mobile Epidural Trial (COMET2).

dictated by a long-term outcome of lower prevalence (new chronic backache after epidural). The analysis of long-term outcomes is ongoing, and the results are not presented here.

The results presented here represent an analysis of prespecified anesthetic outcomes. It was considered that a sample size of 1,050 women would detect any clinically important differences in normal vaginal delivery rates with a high probability and be more than adequate for the prespecified secondary outcomes presented.

Randomization to the trial was performed by the duty anesthesiologist using a randomization computer situated on the labor ward. The program was devised by clinical trials experts separate from the study team, in order to exclude bias. The program included minimization for maternal age and ethnic group. Unfortunately, an error in programming that allocated women according to age resulted in a severe imbalance in age and ethnic distributions in the trial sample (COMET1). Two independent groups of national experts in clinical trials analysis were immediately commissioned, one by the research team and one by the funding body, and repeat recruitment of a further complete sample was recommended. It was prespecified that the second sample (COMET2) be regarded as the primary data set, the results of which are presented here. Secondary outcomes from COMET1 have not been analyzed or presented, since the sample is age-imbalanced.

Blinding to trial technique of the mother or those in attendance was not possible, but the trial midwives were not informed of study group allocation prior to postpartum interview, and the study group code was not broken until completion of recruitment. No results from COMET1 were provided to anyone involved in recruitment to the COMET2 sample. Obstetric management followed usual clinical practice (dictated by the labor ward guidelines).

Statistical Analysis

Statistical analysis was conducted with SPSS for Windows (SPSS UK Ltd., Woking, Surrey, United Kingdom) using chi-square tests for discrete variables and the Mann–Whitney U test for VAS measurements.

Analysis was performed on an intention-to-treat basis. The small number of women recruited to the trial who delivered before an epidural could be sited or who received an epidural technique different from that of their randomized trial arm (fig. 1) were analyzed in the trial arm to which they had been allocated. Women in whom the spinal element of the CSE failed or who suffered inadvertent dural puncture were analyzed in the trial arm to which they had been allocated.

All comparisons were between each mobile technique separately relative to traditional, not between mobile groups. In view of multiple hypothesis testing, significance levels for prespecified secondary outcomes were taken as $P < 0.01$.

Results

We recruited 1,054 nulliparous women requesting epidural for pain relief to the COMET2 sample, a 55% recruitment rate (24 h/day) from eligible women (fig. 1). The most common reason for nonrecruitment was women not being asked to take part in the trial by the duty anesthesiologist. A total of 353 women were randomized to the traditional group, 351 to the CSE group,

Table 1. Characteristics of Women and Infants in COMET 2 by Study Group

	Study Group		
	Trad (n = 353)	CSE (n = 351)	LDI (n = 350)
Age (yr) (SD)	26.5 (5.9)	26.5 (5.8)	26.6 (5.9)
Ethnic group (%)	—	—	—
Caucasian	302 (85.6)	302 (86.0)	298 (85.1)
Other	51 (14.4)	49 (14.0)	52 (14.9)
Booking weight (kg) (SD)	66.5 (13.6)	65.3 (14.3)	67.6 (14.0)
Induced onset of labor (%)	153 (43.3)	140 (39.9)	162 (46.3)
Pregnancy induced hypertension (PIH) (%)	45 (13)	45 (13)	61 (17)
Received meperidine > 4 h previously	51 (14%)	59 (17%)	46 (13%)
Cervical dilatation (%)	—	—	—
≤ 2 cm	122 (34.5)	100 (28.5)	102 (29.1)
3–5 cm	175 (49.6)	192 (54.7)	189 (54.0)
Gestational age (weeks) (%)	—	—	—
≤ 37	27 (7.7)	24 (6.9)	25 (7.3)
≥ 41	142 (40.2)	146 (41.6)	145 (41.4)
Birthweight (g) (SD)	3,363 (542)	3,365 (560)	3,349 (512)
Median VAS before epidural	75	78	75

Values reported as means (SD = standard deviation) or numbers in each group (% of group).

COMET = Comparative Obstetric Mobile Epidural Trial; Trad = traditional; CSE = combined spinal–epidural; LDI = low dose infusion.

and 350 to the LDI group. Only 6 women (0.6%) were given a different technique from that allocated. Five of these were the result of low-dose techniques converted to traditional, commonly because of equipment (infusion pump) failure. Sixteen women (1.5%) delivered before an epidural could be sited.

Details of the study groups are given in table 1 and show that maternal and neonatal characteristics were similar. The majority of epidurals were inserted with the patient in the sitting position (76%), with a loss of resistance to saline technique (81%) in the L2–L3 or L3–L4 spinal interspaces (45% and 51%, respectively). There were no differences in any of these characteristics between trial groups.

Technical Difficulties

Details of difficulties in the conduct of epidural analgesia are shown in table 2. Of the 4 women in whom inadvertent dural tap with an epidural needle occurred, two had an epidural successfully sited at another spinal interspace, one had intermittent spinal analgesia *via* an intrathecal catheter, and the epidural was abandoned in the other. One woman required an epidural blood patch for postdural puncture headache. There were no reports of postdural puncture headache requiring blood patch from the deliberate spinal needle dural puncture in the CSE group. In 25 of the 351 women allocated to the CSE group, the deliberate dural puncture for the spinal component of the CSE was not achieved in the only attempt allowed in the protocol. The only significant difference in technical difficulties between techniques was a higher incidence of difficult epidural insertion in the CSE group reported by anesthesiologists, excluding the cases of "failed spinal."

Table 2. Technical Difficulties at Epidural Insertion (Excluding Failed Spinal in CSE) by Study Group

	Study Group		
	Trad (n = 353)	CSE (n = 351)	LDI (n = 350)
Failed epidural	2	5	7
Difficult insertion	48	68*	44
Dural tap	1	0	3
Bloody tap	14	13	17
Resisted (any time after first analgesia)	15	14	24

* $P < 0.001$ chi-squared. N.B. tests of significance conducted for CSE *vs.* Trad and LDI *vs.* Trad.

Trad = traditional; CSE = combined spinal–epidural; LDI = low dose infusion.

Drug Doses

Drug utilization for each technique is presented in table 3 along with the duration of first and second stages of labor for each epidural technique. The similarity between the duration of first and second stages between groups means that mean dose values may be compared directly. Throughout labor (first and second stages), the mean (milligram) usage of bupivacaine per woman, excluding top-ups for operative procedures, was similar in the traditional and LDI groups but significantly lower in the CSE group. Less fentanyl was used in the CSE group than in the LDI group. Among instrumental deliveries, the proportion in each group requiring epidural top-up for the procedure was the same (traditional, 67 of 131; CSE, 57 of 102; LDI, 55 of 98). The doses of bupivacaine and fentanyl administered for operative intervention, including cesarean and instrumental vaginal delivery, were no different between epidural techniques.

Excluding drugs given for instrumental or operative delivery, rescue analgesia of bupivacaine 0.25% or higher

Table 3. Duration of Stages of Labor (min) and Drug Use by Stage of Labor and Study Groups

	Study Group		
	Trad n = 353	CSE n = 351	LDI n = 350
First stage of labor	—	—	—
Mean duration (min) (SD)	514 (274)	530 (277)	526 (289)
Mean bupivacaine dose (mg) (SD)	91.2 (51.3)	47.7(38.1)†	84.9 (52.5)
Mean fentanyl dose (μg) (SD)	—	96.9 (53.7)	150.6 (93)
Second stage of labor	—	—	—
Mean duration (min) (SD)	108 (63)	102 (64)	105 (68)
Mean bupivacaine dose (mg) (SD)	12.6 (22.9)	8.7 (17.9)*	16.2 (18.8)
Mean fentanyl dose (μg) (SD)	—	10.4 (18.9)	12.2 (30.6)

* $P < 0.01$, † $P < 0.001$ Chi-Squared. N.B. tests of significance conducted for CSE *vs.* Trad and LDI *vs.* Trad.
Trad = traditional; CSE = combined spinal–epidural; LDI = low dose infusion.

concentration, at least once, was given to 80 women in the CSE and 86 women in the LDI groups. This compares to a similar number in the traditional group (n = 78) requiring at least one dose of fentanyl to supplement analgesia during labor.

For women requiring delivery by cesarean section, the epidural was used in 85 women in the traditional group, 90 in the CSE group, and 92 in the LDI group, and general anesthesia was used in 21, 14, and 15 women in the three groups, respectively. The most common reasons for general anesthesia were insufficient time to achieve an adequate block and maternal preference.

Pain Relief Assessments

The median VAS score recorded prior to epidural insertion was similar in each group (table 1). The high values are consistent with pain from labor. Table 4 depicts median VAS score recorded in labor and thereafter, up to 10 h after epidural insertion, for each epidural technique. It also shows the proportion of VAS scores less than 20 at each time. At 10 h after insertion, the numbers in each group who had not already delivered were very small; therefore, values are shown only up to this point.

At 5 min after insertion, the median VAS score reported in the CSE group was significantly less than that of the traditional group, and this difference was maintained up to 1 h. For the first 30 min after insertion, a significantly greater proportion of VAS scores less than 20 are recorded in the CSE group compared with the traditional group. At 3 h, the median VAS score in the CSE group was significantly higher than that of the traditional group, and there were fewer VAS scores less than 20 in the CSE group. This did not coincide with the mean time to first epidural to-up, after spinal analgesia,

Table 4. Median Visual Analogue Pain Scores (VAS) during Labor and Percentage of Women Reporting VAS < 20/100 (% VAS < 20) by Study Group, after Epidural Insertion

	VAS for Epidural Technique Allocated						
	Traditional (n = 353)		CSE (n = 351)		LDI (n = 350)		
Time after Insertion	VAS (median)	% VAS < 20	VAS (median)	% VAS < 20	VAS (median)	% VAS < 20	N (Total) 1,054
5 min	64	8%	20†	50%†	57	13%	939
10 min	44	24%	0†	69%†	38	26%	941
15 min	27	43%	0†	74%†	28	38%	955
20 min	12	57%	0†	80%†	18	52%	945
25 min	7	65%	0†	83%†	10	55%	941
30 min	0	71%	0†	84%†	9*	60%	936
1 h	14	59%	4†	66%	10	63%*	881
2 h	15	55%	12	60%	11	58%	825
3 h	15	56%	21*	44%*	12	59%	730
4 h	10	56%	20	49%	10	61%	589
5 h	18	52%	21	48%	10	60%	477
6 h	20	49%	20	49%	10	62%	363
7 h	20	48%	15	52%	7	64%	257
8 h	28	46%	25	44%	9	60%	185
9 h	22	47%	20	47%	6	66%	111
10 h	20	45%	42	35%	0	69%	72

* $P < 0.01$, † $P < 0.001$, (Mann–Whitney U test). N.B. tests of significance conducted for CSE *vs.* Trad and LDI *vs.* Trad.

Table 5. Efficacy of Pain Relief at Birth by Study Group in Women with Spontaneous Vaginal Delivery

	Study group		
	Trad n = 124	CSE n = 150	LDI n = 150
Maternal pain report at the time of delivery	—	—	—
Comfortable– no sensation	12 (13%)	18 (16%)	17 (15%)
Comfortable– sensation	50 (55%)	45 (40%)	51 (45%)
Painful	29 (32%)	50 (44%)	46 (40%)
Missing	33	37	36
Median VAS for pain at birth, at delivery	40	55	40
(% VAS < 20)	(20)	(17)	(23)
Missing	43	54	50
Median VAS for pain at birth, at PNI	27	47	32
(% VAS < 20)	(38)	(30)	(43)
Missing	0	0	1

Assessments by women at delivery are numbers (% of group).Visual analog pain scores (VAS) at delivery and postnatal interview (PNI) are median values (% group with VAS < 20).

Trad = traditional; CSE = combined spinal–epidural; LDI = low dose infusion.

in the CSE group (mean, 87 min; SD, 40 min). There were no differences in VAS between these groups up to 10 h thereafter.

Median VAS score and the proportion of VAS scores less than 20 for the LDI group were significantly different from those of the traditional group only at one time point each, 30 min and 1 h after epidural insertion, respectively.

More women had satisfactory analgesia with CSE (94%) than with traditional (87%) analgesia when assessed by the anesthesiologist at 30 min after insertion. There were no differences between the traditional and LDI (81%) groups for this assessment.

Pain assessments for birth in women with spontaneous vaginal deliveries only are presented in table 5. Median VAS score for birth recorded at the time of delivery and at postpartum interview were proportionately but not significantly higher in the CSE group relative to the traditional group.

Anesthesiologist Reattendance

Table 6 shows the proportion of epidurals within each group requiring reattendance of an anesthesiologist in the preceding hour, as a percentage of the number of epidurals in that group at the time stated (numbers decrease with time as deliveries occur). The CSE protocol stipulated that all first epidural top-ups were to be given by an anesthesiologist; however, there were significantly more attendances required after this time. The LDI group also showed significantly more attendances at 3 and 4 h after insertion.

Discussion

This randomized controlled trial has demonstrated that the beneficial impact of mobile epidural techniques on delivery mode[5] does not compromise any aspect of pain relief during labor. Indeed, we have demonstrated that a CSE technique provides better analgesia than the traditional technique in the first hour after epidural insertion. Furthermore, mobile epidurals may be introduced into practice with a minimum of technical difficulty and only a moderate increase in reattendance rate by anesthesiologists.

Our study population represented a broad spectrum of nulliparous women requesting epidural analgesia. This

Table 6. Requirement for Anesthesiologist Reattendance in Preceding Hour, as a Percentage of Epidurals at Time Reported by Study Group

	Percentage of Epidurals in Each Group Requiring Anesthesiologist Attendance in Preceding Hour			Number of Records at Time (T)
Time (T) after Epidural Insertion	Trad (n = 353)	CSE (n = 351)	LDI (n = 350)	N = 1054
1 h	10	39**	15	881
2 h	9	40**	13	825
3 h	10	18*	17*	730
4 h	8	13	15*	589
5 h	9	17*	10	477
6 h	13	11	14	363
7 h	7	11	10	258
8 h	16	13	10	185

*$P < 0.01$, **$P < 0.001$ chi-squared. N.B. tests of significance conducted for CSE *vs.* Trad and LDI *vs.* Trad.

Trad = traditional; CSE = combined spinal–epidural; LDI = low dose infusion.

contrasts with the randomized controlled trial of Nageotte *et al.*,[4] which included only "low-risk" singleton nulliparae with cephalic presentation, in spontaneous labor. Our study population had a high proportion of women with induced labor and included multiple pregnancies and women with pregnancy-induced hypertension and was therefore representative of women commonly requesting epidural analgesia. This is likely to account for the low overall spontaneous vaginal delivery rate (40%). Recruitment was achieved "around the clock," including more than 50% of eligible patients, and results at both participating centers were similar (data not presented). Thus, the results can be generalized to labor ward practice that includes tertiary obstetric care.

The choice of mobile epidural technique reflected the developments in practice at the time of trial design. The CSE protocol is almost identical to that described by Collis *et al.*[2] in the original work on maternal satisfaction associated with this technique.***

Studies from the United States suggested that satisfactory analgesia could be achieved with "ultra low-dose" bupivacaine mixtures administered by infusion.[9] Piloting this ultra low-dose infusion technique, utilizing 0.04% bupivacaine with 1.67 μg/ml fentanyl in more than 60 women at one of our trial units, we could not reproduce effective pain relief, with satisfactory analgesia reported in only 11% of women. Thus, 0.1% bupivacaine with 2 μg/ml fentanyl was chosen for both LDI and CSE groups, since it offered effective pain relief and still allowed mobility.

Since neither participating unit offered mobile epidurals as standard prior to the trial, there were significant issues of implementation and education associated with their introduction. All first epidural top-ups in each group were administered by anesthesiologists. Subsequent intermittent top-up of epidurals by trained midwifery staff is common practice in the United Kingdom. Thus, fixed-rate infusion in a closed system, supplemented by intermittent top-ups, was chosen to maximize familiarity and enhance safety of administration.

Our findings of technical difficulties experienced at epidural insertion are relevant to implementation. The higher incidence of difficult epidural insertion reported in the CSE group might reflect unfamiliarity with the technique and the inevitable consequences of learning a new practical skill. However, since experience with CSE had been acquired by some anesthesiology staff during COMET1 and pilot studies, this result may reflect a regional technique that is genuinely more technically demanding to perform. Inadvertent dural puncture occurred rarely. There were only four dural taps with the Tuohy needle (0.38%). The fact that none occurred in the CSE group is most likely the result of the chance distribution of a rare event but is reassuring regarding the safety of this procedure.

The effectiveness of analgesia could have been examined in a number of ways. Since VAS values are not normally distributed, comparing means is statistically invalid. We chose two ways of quantifying pain scores. As a measure of central tendency, median VAS is far less sensitive to extreme scores than mean values and is an accepted tool in assessing pain. However, the subtleties of differences in distribution of VAS may still be obscured; therefore, we chose to supplement median values by reporting the proportion of the group (as a percentage) with pain scores less than a value (20) chosen to be consistent with effective pain relief, albeit arbitrarily.

Both methods of assessing pain showed that within 5 min of epidural insertion, analgesia with CSE was superior to that obtained with the traditional technique. This was sustained throughout the first hour. However, at 3 h, both median VAS score and VAS scores less than 20 were significantly worse in the CSE group. This trend did not continue, and analgesia from traditional and CSE techniques thereafter were indistinguishable. Increased maternal satisfaction with CSE has been previously reported,[2] and single-agent intrathecal opioid injection has been shown to provide benefits to the quality of analgesia in early labor.[10,11] Our finding of enhanced efficacy of CSE for the first hour after insertion adds weight to these previous observations and provides a more robust scientific evaluation, since it is based on maternal VAS during labor from a large population. The profound pain relief associated with CSE may be an effect of intrathecal opioids (fentanyl) or a sustained effect of spinal local anesthetic (bupivacaine) even an hour after administration. The efficacy of initial analgesia, as perceived by the anesthesiologist, mirrored these findings.

Pain at the time of the birth, assessed at postpartum interview and at delivery itself, both suggest that CSE may not be as effective as traditional analgesia at this stage, although, since only normal vaginal deliveries could be considered, the differences were not statistically significant. If women in the CSE group do indeed suffer more pain at delivery, it could be the result of the "intermittent bolus" protocol used for the technique, if top-ups were not given often enough during the second stage of labor.

It is noteworthy that LDI provided similar onset of analgesia to traditional analgesia, given the greatly reduced concentration of local anesthetic utilized. At 30 min after insertion, although the proportion of patients with a VAS score less than 20 did not differ, there was a significantly higher median VAS score in the LDI group. However, the median VAS scores in both groups at this stage were very low and consistent with effective analgesia. It is therefore questionable whether this statistical difference is of clinical relevance. Thereafter, during labor and at delivery, the analgesia provided by LDI was indistinguishable from traditional.

We have examined both contemporaneous assessments of labor pain and an overall perception 24 h later. Although the latter was the main prespecified pain relief assessment of the trial, it was difficult to decide which was of greater importance. The results, however, are broadly in accord with each other, highlighting the effectiveness of epidural analgesia *per se*. It may be equally useful to examine the pain remembered at some more distant time, an assessment of which is included in our follow-up questionnaire 12 months after delivery (not presented), since this perception may have a greater influence on future choices of pain relief for childbirth.

Drug doses for the mobile techniques were notably different. The mean dose of bupivacaine delivered by the traditional technique was similar to that used in the LDI group. However, CSE mean doses for bupivacaine and fentanyl were roughly half those of LDI. This is likely to result from the intermittent bolus protocol chosen to administer the CSE technique. These differences raise two important issues. Despite differences in mean drug doses, CSE achieved adequate pain relief; however, the impact of CSE and LDI on delivery mode previously reported[5] were similar. This suggests that the local anesthetic concentration to which sensory and motor pathways are exposed may be as important in determining delivery outcome as the absolute dose of local anesthetic received. As a matter of conjecture, there may be a threshold of peripheral motor–sensory blockade beyond which epidural analgesia is associated with detrimental effects on instrumental intervention. Our results would be consistent with this threshold having been surpassed by traditional epidural analgesia but not by either mobile technique, despite the differences in drug doses. While our study did not seek evidence for such an effect, an examination of the detailed lower limb motor power and maternal ambulation data collected during the COMET study may yield interesting results in this context and will be reported elsewhere.

Anesthesiologist reattendance is only one indicator of the workload associated with each epidural technique. However, it provides a useful assessment of the comparative input required from anesthesiologists and is pertinent to units contemplating the introduction of mobile techniques. Although reattendance was generally low, both mobile techniques were associated with an increased requirement in the first 5 h. However, this must be offset against the potential reduction in workload from instrumental intervention. A full cost-effectiveness analysis of the techniques, including clinician time, showed no difference in overall costs attributed to each technique and will be reported elsewhere.

In conclusion, we have presented evidence that both these mobile techniques are effective, safe, and easy to introduce. Given the proven benefit to obstetric outcome, the case for the uniform introduction of mobile epidurals into labor ward practice and the abandonment of traditional epidural techniques would seem irrefutable.

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Appendix

The trial was initiated and coordinated by Christine MacArthur and Andrew Shennan (principal investigators), who obtained funding together with Debra Bick, Griselda Cooper, Margo Lewis, and Anne May (joint applicants). They were assisted by Chris Elton, who, together with Anne May, set up the trial in Leicester. All the following individuals comprised the trial design team. *Writing committee:* Matthew J. A. Wilson, Griselda Cooper, Christine MacArthur, and Andrew Shennan. *Birmingham Center (Departments of Public Health and Epidemiology and Anesthesiology, University of Birmingham, Birmingham, United Kingdom):* Christine MacArthur, Ph.D., Professor of Maternal and Child Epidemiology; Griselda Cooper, F.R.C.A., Senior Lecturer in Anesthesiology; Jennifer Whyte, F.R.C.A., Lecturer in Anesthesiology; Debra Bick, M.Med.Sc., Lecturer in Midwifery; Lynne Crewe, B.Sc., Research Midwife; Helen Garston, F.R.C.A., Specialist Registrar in Anesthesiology; Lisa Gold, M.Sc., Lecturer in Health Economics; Robert Lancashire, B.A., Computer Officer; Margo Lewis, F.R.C.A., Consultant Anesthesiologist; Phillip Moore, F.R.C.A., Research Fellow in Anesthesiology; Matthew Wilson, F.R.C.A., Lecturer in Anesthesiology. *Leicester Center (Leicester Royal Infirmary Departments of Anaesthesia and Obstetrics, Leicester, United Kingdom):* Andrew Shennan, M.D., M.R.C.O.G., Senior Lecturer in Obstetrics and Gynaecology (St.

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This team and the researchers met regularly as a steering group, and all contributed to trial management. The team included Lisa Gold, who also addressed health economic issues. Aidan Halligan and Michael de Swiet were involved in initial study design and were joint applicants. The trial anesthetic techniques and intrapartum protocols were developed by Jennifer Whyte, Matthew Wilson, and Nicola Hickman (Research Anesthetists). Lynne Crewe and Molly Patterson, B.Sc. (Research Midwives), together with the research anesthesiologists, were responsible for ensuring recruitment, data collection, and entry and training duty anesthesiologists and midwives. Walayat Hussain assisted with recruitment in COMET 1. Patricia Squire was an additional research midwife for COMET 2, and additional research anesthesiologists included Samina Bharmal, Helen Garston, and Philip Moore, who had similar responsibilities as the above research staff. Matthew Wilson and Robert Lancashire performed the analysis. All members of the writing committee were involved in interpretation of results and approved the final manuscript.