Effect of low-dose mobile versus traditional epidural techniques on mode of delivery: a randomised controlled trial

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

Summary

Background Epidural analgesia is the most effective labour pain relief but is associated with increased rates of instrumental vaginal delivery and other effects, which might be related to the poor motor function associated with traditional epidural. New techniques that preserve motor function could reduce obstetric intervention. We did a randomised controlled trial to compare low-dose combined spinal epidural and low-dose infusion (mobile) techniques with traditional epidural technique.

Methods Between Feb 1, 1999, and April 30, 2000, we randomly assigned 1054 nulliparous women requesting epidural pain relief to traditional (n=353), low-dose combined spinal epidural (n=351), or low-dose infusion epidural (n=350). Primary outcome was mode of delivery, and secondary outcomes were progress of labour, efficacy of procedure, and effect on neonates. We obtained data during labour and interviewed women postnatally.

Findings The normal vaginal delivery rate was 35·1% in the traditional epidural group, 42·7% in the low-dose combined spinal group (odds ratio 1·38 [95% CI 1·01–1·89]; p=0·04); and 42·9% in the low-dose infusion group (1·39 [1·01–1·90]; p=0·04). These differences were accounted for by a reduction in instrumental vaginal delivery. Overall, 5 min APGAR scores of 7 or less were more frequent with low-dose technique. High-level resuscitation was more frequent in the low-dose infusion group.

Interpretation The use of low-dose epidural techniques for labour analgesia has benefits for delivery outcome. Continued routine use of traditional epidurals might not be justified.

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Introduction

Epidural analgesia is used for pain relief in labour by more than 150 000 women every year in the UK, and many more worldwide.[1,2] It is the most effective form of pain relief during labour but is associated with increased rates of instrumental vaginal delivery, prolonged labour, and oxytocin augmentation.[3] Epidural analgesia does not seem to affect the likelihood of caesarean section delivery.[3] Findings that show adverse effects are from trials based on traditional epidural analgesia, which usually results in dense paralysis of motor functions (ie, block). Some of the adverse events might be related to this motor paralysis, which can affect pelvic floor tone, mobility, and ability to push during labour.

New forms of epidural analgesia use combinations of opioid and less concentrated local anaesthetic which preserves maternal motor function, and allow parturients to walk about. However, these low-dose epidurals are used only in a minority of units.[2]

Although low-dose techniques have been associated with increased maternal satisfaction,[4,5] effects on obstetric outcome are uncertain. Nageotte and colleagues[6] in the USA showed a reduction in instrumental vaginal delivery rate with a combined spinal epidural—a technique that is more controversial in the UK.[7] They studied nulliparous women who had spontaneous labour at full term. Women in spontaneous labour are much less likely to receive epidural because those who are induced have long labours and therefore request analgesia more often. Several low-dose epidural techniques are available, which might have a differential effect on paralysis of motor functions. For example, continuous infusion, a commonly used technique,[2] is associated with a higher total dose of local anaesthetic than intermittent anaesthetic top-ups, to achieve equivalent analgesia.

We did a randomised controlled trial (Comparative Obstetric Mobile Epidural Trial, COMET), to compare traditional epidural analgesia for labour with two types of low-dose techniques—combined spinal and continuous infusion.

Methods

Patients

Our study population included all nulliparous women who requested epidural for pain relief during labour in two maternity units between Aug 1, 1997, and April 30, 2000. The exclusion criteria were: contraindication to epidural analgesia, previous epidural or spinal procedure, imminent delivery, or injection of pethidine within the previous 4 h. All nulliparous women who had planned to deliver at each unit were sent a study information leaflet and questionnaire about pregnancy symptoms and labour plans at 34 weeks' gestation (data not shown). We gave women further information when they requested an epidural during delivery, and the duty anaesthetist obtained written consent. This study was approved by local research ethics committees in both centres.

Randomisation

The duty anaesthetist randomly assigned women to receive traditional epidural, low-dose combined spinal epidural, or low-dose infusion technique using a customised randomisation programme situated on the delivery suite. The programme was provided by clinical trials experts, separate from the study team, to exclude bias. The programme included minimisation to balance maternal age and ethnicity but unfortunately an error in the programme that assigned women according to age resulted in a severe imbalance in distribution between the groups for age and ethnic origin (table 1). Both we and the funding body immediately commissioned two independent groups of national experts in clinical trials analysis who recommended repeat recruitment of a further complete sample. This second sample was referred to as COMET2 and regarded as the primary data set. Data from the first sample (COMET1) and COMET 1 and 2 combined are also presented, with appropriate standardisation for the main outcome (table 1). Therefore, we recruited 1054 women twice.

We could not conceal the trial technique group from the mother or individuals in attendance. To prevent bias, none of the investigators were involved in any decisions about obstetric management (ie, those who decided mode of delivery had no vested interest in the outcome). Management of mothers was in accordance with the labour ward guidelines. Trial midwives were not informed of study group assignment before postpartum interview. The study group code was not revealed until completion of recruitment. We did not provide results from COMET1 to investigators who recruited women to the COMET2 sample.

Epidural techniques

In each group we gave women 500 mL Hartmann's solution intravenously via a wide-bore cannula. Epidurals were sited with a 16 gauge Tuohy needle (Sims Portex, Hythe, UK) in a suitable lumbar interspace with loss of resistance technique while the mother was sitting or lying on her side according to operator preference. Mothers in the traditional epidural group had a test dose of 3 mL lidocaine 2% (60 mg). After 5 min, analgesia was initiated with 10 mL bupivacaine 0·25% (25 mg). We provided subsequent boluses of 10 mL bupivacaine 0·25% (25 mg) on request, but no more than hourly.

Characteristic	Traditional epidural (n=388)	Combined spinal epidural (n=335)	Low-dose infusion (n=331)
Age			
⩽19	1 (0·3%)	69 (21%)	73 (22%)
20–24	12 (3%)	110 (33%)	100 (30%)
25–29	131 (34%)	111 (33%)	117 (35%)
30–34	208 (54%)	17 (5%)	16 (5%)
⩾35	36 (9%)	28 (8%)	25 (8%)
Ethnic group			
White	322 (83%)	301 (90%)	298 (90%)
Asian	43 (11%)	24 (7%)	26 (8%)
Other	23 (6%)	10 (3%)	7 (2%)
Mode of delivery			
Spontaneous vaginal	118 (30%)	153 (46%)	159 (48%)
Instrumental vaginal	160 (41%)	107 (32%)	105 (32%)
Caesarean section	110 (28%)	75 (22%)	67 (20%)

Values are numbers (%). The age-standardised odds ratio for normal vaginal delivery for COMET1 was 0·91 (95% CI 0·62–1·37) for the combined spinal group and 1·05 (0·70–1·61) for the low-dose infusion group, relative to the traditional group; the respective values for the aggregated ratios for COMET1 and COMET2 were 1·20 (0·94–1·54) and 1·27 (0·98–1·61). The COMET1 and COMET2 age-standardised data did not differ (χ^2 test for interaction low-dose infusion p=0·10 and combined spinal epidural p=0·28).

Table 1: **COMET1 data**

For both mobile techniques we used a low-dose mixture of bupivacaine 0·1% with fentanyl (2 μg/mL). For mothers in the combined spinal epidural group we established analgesia by an intrathecal injection, via a 24 gauge Sprotte (Pajunk, Geisingen, Germany) needle of 1 mL bupivacaine (0·25%) and 25 μg fentanyl (total volume 1·5 mL) using a needle-through-needle method. As the spinal block wore off, 15 mL of low-dose mixture (bupivacaine 15 mg, fentanyl 30 μg) was given via the epidural catheter. We gave mothers subsequent analgesia intermittently in boluses of 10 mL low-dose mixture on request, but no more than every half hour. Only one attempt at subarachnoid injection was allowed: if this attempt failed we established epidural block immediately with 15 mL of low-dose mixture. Mothers in the low-dose infusion group had an epidural injection of 15 mL of low-dose mixture with no previous test dose. We gave an infusion of low-dose mixture at 10 mL per h, via a portable Baxter pump.

Rescue analgesia in the traditional group included 50 μg of fentanyl, or more concentrated bupivacaine solutions. For the spinal epidural and low-dose infusion groups initial rescue analgesia consisted of a further 10 mL bolus of low-dose mixture. We used 0·25% bupivacaine if necessary. We gave mothers who had instrumental and operative deliveries appropriate doses of local anaesthetic according to local guidelines. Analgesia was maintained throughout the first and second stage of labour.

Data collection

The duty anaesthetist and midwife obtained detailed data throughout labour, and research midwives interviewed women 24–48 h after delivery on the postnatal ward. Long-term data were also collected by postal questionnaire 12 months after delivery, but this follow-up is in progress. The primary prespecified short-term outcome measure was mode of delivery. We assessed this outcome by first examining the normal vaginal delivery rates, then by separating the types of operative delivery (caesarean section or instrumental vaginal delivery), to establish what might account for any differences.

Our secondary outcomes were progress of labour, efficacy of procedure, and effect on the neonates. We assessed progress of labour by noting the duration of first and second stages of labour, pushing time, and oxytocin augmentation. We made regular assessments of pain throughout labour and again postnatally, but the prespecified main assessment of pain relief efficacy was the mother's estimate of how painful labour was after the epidural was inserted. We obtained the main assessment by asking the mothers to complete a visual analogue scale (0–100; 0=no pain, 100=as much pain as I could imagine) during the postnatal interview. We also assessed women's perceptions of their ability to push by asking how often they had sensations to let them know when they needed to push. Our prespecified main assessment of neonatal effects was APGAR score at 5 min after birth. Other neonatal outcomes were APGAR score at 1 min, resuscitation requirements, and admission of the baby to the special care unit. At enrolment we recorded maternal age, ethnic origin, height, and weight taken at the initial antenatal appointment. We also recorded relevant obstetric characteristics, including pregnancy-induced hypertension, induction of labour, and cervical dilation at epidural insertion. Birthweight was recorded after delivery.

We also did detailed assessments of maternal mobility, drug doses, and adverse epidural effects throughout labour. The anaesthetist assessed motor power in each

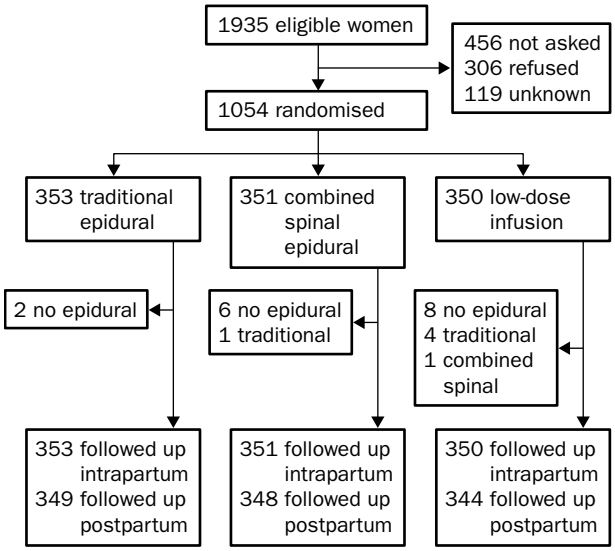
leg of the mother using Breen's modification of the Bromage score[8] at 30 min, then hourly after the epidural had been given. Women in the combined spinal epidural and low-dose infusion groups who were able to partly bend their knees were encouraged to move. For women who were able to stand, we assessed proprioception at 30 min using Romberg's sign. To assess actual mobility, we recorded the maximum amount of movement (walk, stand, or sit in a chair) each hour.

Statistical analysis

We also examined long-term outcomes (data not shown), for which the power calculation required 350 women in each group. Power calculations for mode of delivery were based on data from Queen Charlotte's Hospital, UK, where combined spinal epidural 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-β) and 5% significance level (two sided α) would require 180 women in each group. Therefore, we judged that a sample of 350 women would detect any clinically important differences in normal vaginal delivery rates with a high probability and would, therefore, be more than adequate to make primary short-term comparisons. We did statistical analysis with SPSS for Windows (version 10), using χ^2 tests for discrete variables, and Mann-Whitney *U* test for the visual analogue scale measures. Odds ratios with 95% CI were calculated for the primary outcomes. We did our analysis on an intention-to-treat basis and made separately all comparisons between the mobile technique and the traditional groups.

Results

We enrolled 1054 nulliparous women requesting epidural for pain relief to the COMET2 sample, a 55% recruitment rate from eligible women (figure). The most common reason for non-recruitment was that women were not asked to take part in the trial by the duty anaesthetist. 353 women were randomly assigned to traditional, 351 to combined spinal, and 350 to low-dose infusion group and almost all received their allocated technique. 16 (2%) women delivered before the epidural could be inserted and six (1%) were given a different method from that allocated. Of these six, five had their assigned low-dose infusion converted to traditional, usually because of equipment (pump) failure. Main outcome data were obtained for all women, and only 13 (1%) were not interviewed postpartum (figure). Table 2 shows characteristics of the study groups.



Trial profile (COMET2)

	Traditional epidural (n=353)	Combined spinal epidural (n=351)	Low-dose infusion epidural (n=350)
Age (years)			
⩽19	52 (15%)	49 (14%)	52 (15%)
20–24	78 (22%)	80 (23%)	78 (22%)
25–29	109 (31%)	107 (31%)	108 (31%)
30–34	82 (23%)	83 (24%)	79 (23%)
⩾35	32 (9%)	32 (9%)	33 (9%)
Ethnic origin			
White	302 (86%)	302 (86%)	298 (85%)
Asian	36 (10%)	34 (10%)	38 (11%)
Other	15 (4%)	15 (4%)	14 (4%)
Maternal height (cm, mean [SD])	162·8 (6·7)	162·3 (6·7)	163·4 (7·2)
Maternal weight (kg, mean [SD])	66·5 (13·6)	65·3 (14·3)	67·6 (14·0)
Pregnancy-induced hypertension	45 (13%)	45 (13%)	61 (17%)
Induced labour	153 (43%)	140 (40%)	162 (46%)
Prostaglandins	88 (25%)	81 (23%)	88 (25%)
Oxytocin	120 (34%)	113 (32%)	120 (34%)
Cervical dilation			
⩽2 cm	122 (35%)	100 (29%)	102 (29%)
3–5 cm	175 (50%)	192 (55%)	189 (54%)
Pre-block pain VAS score (median [range])	75 (0–100%)	78 (0–100%)	75 (0–100%)
Weeks' gestation*			
⩽37	27 (8%)	24 (7%)	25 (7%)
⩾41	142 (40·2%)	146 (41·6%)	145 (41·4%)
Birthweight (g, mean [SD])	3363 (542)	3365 (560)	3349 (512)

Values are numbers (%) of women unless otherwise indicated. VAS=visual analogue scale. *Completed weeks.

Table 2: **Characteristics of mothers and neonates (COMET2)**

The normal vaginal delivery rate was increased by 7·6% in the combined spinal group and by 7·8% in the low-dose infusion group, compared with the traditional group. The spontaneous vaginal delivery rate was higher in the combined spinal group (odds ratio=1·38 [95% CI 1·01–1·89]) and the low-dose infusion group (1·39 [1·01–1·90]), than in the traditional group (table 3).

Table 3 shows the proportions of instrumental vaginal deliveries and caesarean sections in the three groups. Among women who had vaginal births, the odds ratio of having a normal delivery with combined spinal epidural relative to traditional was 1·55 (95% CI 1·08–2·24) and 1·62 for low-dose infusion (1·12–2·34). The caesarean section rate in each group was similar. For mothers in traditional, combined spinal, and low-dose infusion groups, indications for operative vaginal delivery were delay in the second stage in 79 (60%), 58 (57%), and 51 (52%), and fetal distress in 42 (32%), 37 (36%) and 40 (41%), respectively. Indications for caesarean section were delay in 50 (51%), 54 (55%), and 57 (56%) and fetal distress; 37 (38%), 41 (41%) and 40 (39%), respectively. There were a few other indications. A greater proportion of women in the combined spinal group (82 [33%]) and low-dose infusion group (85 [34%]) had second stage of labour of 60 min or less

Delivery	Traditional epidural (n=353)	Combined spinal epidural (n=351)	Low-dose infusion epidural (n=350)
Normal vaginal	124 (35%)	150 (43%)	150 (43%)
Instrumental vaginal	131 (37%)	102 (29%)	98 (28%)
Caesarean section	98 (28%)	99 (28%)	102 (29%)

*p=0·04, 1DF for normal *vs* other deliveries.

Table 3: **Mode of delivery**

than in the traditional group (67 [26%]), p=0·15 and p=0·06, respectively. Also, a greater proportion of women had a pushing duration of 60 min or less in the combined spinal group (145 [58%]) and in the low-dose infusion group (156 [63%]) than in the traditional group (131 [51%]), p=0·19 and p=0·01, respectively. Duration of first stage of labour and the use of oxytocin augmentation were similar in all groups.

A greater proportion of women in the low-dose infusion group assessed their own ability to push during labour as present all the time compared with the traditional group (95 [38%] *vs* 71 [28%], p=0·01) but the proportion in the combined spinal group did not differ from that in the traditional group (72 [29%], p=0·77).

Median visual analogue scale scores from the postpartum interview of the severity of labour pain after the epidural was inserted were not significantly different: 14, ten, and 12 for the traditional, combined spinal, and low-dose infusion groups, respectively.

The proportion of APGAR scores of seven or less at 5 min after birth was greater in both low-dose groups, than in the traditional group (table 4). At 1 min there were significantly more babies with low APGAR scores in the low-dose infusion group than in the traditional group, but not in the combined spinal group. Admission to special care and the overall resuscitation requirements did not vary between groups, but significantly more babies in the low-dose infusion group required high-level resuscitation (table 4).

At 30 min after insertion of epidural, most women in the combined spinal and low-dose infusion groups had no detectable weakness of hip flexion (260 [80%] of 324 and 261 [89%] of 295, respectively), and more than half the women achieved knee bend (167 [52%] of 324 and 173 [59%] of 295, respectively), although by 3 h this proportion had reduced to about a quarter (74 [29%] and 53 [22%], respectively). Unsteadiness at the 30 min proprioception test was rare with both techniques, but occurred 26 (7%) times in the combined spinal group and six (2%) times in the low-dose infusion. During labour, more than a third of women in each mobile technique group did actually walk or stand; 133 (38%) versus 128 (37%) in the combined spinal and low-dose infusion, respectively. The mean amount of bupivacaine used throughout labour, excluding top-ups for operative procedure, was similar in the traditional (103·8 mg [SD 56·1]) and low-dose infusion groups (101·1 mg [55·1]), but substantially less (56·4 mg [43·3]) in the combined spinal group. The mean amount of fentanyl used per woman was less in the combined spinal than in the low-dose infusion group (107·3 μg [57·9]) *vs* 179·5 μg (99·0), respectively. For instrumental deliveries the proportion of mothers who needed top-up for the procedure was the same for the traditional, combined spinal, and low-dose infusion groups: 67 (51%) of 131; 57 (56%) of 102; 55 (56%) of 98. Rescue analgesia, excluding that given for operative delivery of bupivacaine at 0·25% or greater, was given at least once to 80 women in the combined spinal and 86 in the low-dose infusion groups. Four inadvertent dural punctures occurred, one in the traditional, none in the combined spinal, and three in the low-dose infusion group.

	Traditional epidural (n=353)	Combined spinal epidural (n=351)*	p	Low-dose infusion epidural (n=350)	p
APGAR at 1 min					
⩽7	38 (11%)	55 (16%)	0·07	64 (18%)	0·01
⩾8+	315 (89%)	295 (84%)		286 (82%)	
APGAR at 5 min					
⩽7	3 (1%)	7 (2%)	0·33	10 (3%)	0·09
⩾8	350 (99%)	343 (98%)		340 (97%)	
Admission to neonatal unit	16 (5%)	10 (3%)	0·33	13 (4%)	0·72
Any resuscitation	88 (25%)	88 (25%)	0·98	98 (28%)	0·40
High-level resuscitation†	5 (1%)	5 (1%)	0·98	16 (5%)	0·02

Values are numbers (%). *One neonate delivered with known lethal congenital abnormality and missing APGAR scores. †One or more of bag and mask, intubation, or naloxone.

Table 4: **Neonatal outcomes**

Discussion

Low-dose epidural analgesia resulted in significantly more normal vaginal deliveries than traditional techniques in an unselected population of nulliparous women. We estimate that almost one in four operative vaginal deliveries could be prevented by the introduction of low-dose epidural analgesia. Although our study was not designed to compare the two low-dose techniques, we believe that both would have the same preventive effect. Caesarean section rates between traditional and low-dose techniques did not differ. The quality of analgesia, as judged by the women after the event, was the same with all methods, therefore the benefit achieved by the low-dose techniques does not compromise pain relief.

Disadvantage to the neonate, as assessed by our prespecified measure of an APGAR of seven or less at 5 min, did not differ significantly between the groups. This outcome, however, was rare and there were more low scores in both low-dose groups than in the traditional group. This finding might be explained by the use of fentanyl, an opioid known to cross to the fetus at the doses used,[9] although previous work has not shown differences in APGAR scores. Fentanyl is given in both low-dose techniques and in a greater total dose in low-dose infusion. Despite the increased high-level resuscitation in the low-dose infusion group, possible adverse effects to the neonate should be weighed against the advantages gained by avoidance of an instrumental delivery.

There are various mechanisms whereby low-dose epidural techniques could result in an increase in normal vaginal deliveries. Less motor block allows mobilisation, including standing or walking, which a third of women chose to do, which might enhance the effects of gravity in aiding descent of the fetal head. Bloom and colleagues[10] showed in a general obstetric population, in which a third of women received epidurals, that walking does not affect normal vaginal delivery rates. However, women might be more mobile in the latter stages of labour, if they have adequate pain relief, which could be when walking is most likely to affect descent of the head. The ability to maintain motor function could also assist both the voluntary and involuntary maternal efforts to give birth in the second stage of labour. The degree of preserved sensation with low-dose techniques is not well known, but if it is large it could also have an effect on ability to push. Women's ability to push was much better in the low-dose infusion than in the traditional group, but not in the combined spinal group. We also suggest that the concentration and method of giving the drug are important factors in delivery outcome. The total dose (mg) of bupivacaine, the drug responsible for loss of motor control, was similar in the traditional and low-dose infusion groups, but despite this fact spontaneous vaginal delivery rates differed.

The overall normal vaginal delivery rate was low (40%), but indicates the unselected nature of the population—ie, all nulliparous women requested an epidural for labour pain relief whereas they did not in Nageotte and colleagues' trial.[6] That study included only spontaneous term labours with vertex presentations. Our study design gives the results a high degree of generalisability. The fact that more than 50% of all eligible women were recruited 24 h a day over 15 months in two centres, as part of the standard obstetric anaesthetic service provision, enhances this generalisability.

Computer randomisation is generally accepted to be a gold standard. This method allows individuals to be registered with the trial, and once randomisation is done investigators cannot alter allocation. We asked an independent body to set up the randomisation programme to ensure that we were unaware of this process, and to prevent bias. A mistake in the computer programme in COMET1, incorrectly allocated women according to their age and ethnic group so that there were far more older women in the traditional epidural group. Since normal vaginal deliveries are strongly associated with age, a low normal vaginal delivery rate in the traditional group was expected and was seen in the basic COMET1 data (table 1). Even after age standardisation (ethnic group was not related to mode of delivery), we believed that COMET1 data could not be relied on because the age distribution was so skewed that there were almost no events in the young women who had traditional epidurals. We prespecified, before any analysis, that COMET2 must be the primary data set, but that COMET1 would also be presented to allow full consideration of all available data by others, as well as to check that results were compatible with COMET2.

We have shown that there are clear advantages in delivery outcome with low-dose techniques rather than traditional epidurals for analgesia in labour. Pain relief is not compromised. The reduced operative intervention with the low-dose techniques needs to be weighed against possible adverse effects on the neonate. Long-term data are not available yet, but in relation to delivery outcome, continued routine use of traditional epidurals might not be justified.

COMET Study Group
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Contributors
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). They were assisted by C Elton who, together with A May, set up the trial in Leicester. All comprised the trial design team. This team and the researchers met regularly as a steering group and all contributed to trial management. The team included L Gold who also addressed health economic issues. A Halligan and M de Swiet (Imperial College) were involved in initial study design and were joint applicants. The trial anaesthetic techniques and intrapartum protocols were developed by J Whyte, M Wilson, and N Hickman (research anaesthetists). 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 COMET1. P Squire was an additional research midwife for COMET2, and additional research anaesthetists were S Bharmal, H Garston, and P Moore, who had similar responsibilities as the above research staff. R Lancashire and C MacArthur did the analysis. All trial contributors were involved in interpretation of results and approved the final report.

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