



## ORIGINAL ARTICLE

# Epidural analgesia and breastfeeding: a randomised controlled trial of epidural techniques with and without fentanyl and a non-epidural comparison group

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## Summary

We compared breastfeeding initiation and duration in 1054 nulliparae randomised to bupivacaine Control epidural, Combined Spinal Epidural or Low Dose Infusion and 351 matched non-epidural comparisons. Women were interviewed after delivery and completed a postal questionnaire at 12 months. Regression analysis determined factors which independently predicted breastfeeding initiation. Breastfeeding duration was subjected to Kaplan–Meier analysis. A similar proportion of women in each epidural group initiated breastfeeding. Women with no epidural did not report a higher initiation rate relative to epidural groups and those who received pethidine reported a lower initiation rate than control epidural ( $p = 0.002$ ). Older age groups ( $p < 0.001$ ) and non-white ethnicity ( $p < 0.026$ ) were predictive of breastfeeding. Epidural fentanyl dose, delivery mode and trial group were not predictive. Mean duration for breastfeeding was similar across epidural groups (Control 13.3, Combined Spinal Epidural 15.5, Low Dose Infusion 15.0 weeks). Our data do not support an effect of epidural fentanyl on breastfeeding initiation.

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The benefits of breastfeeding to infants and mothers are well established but evidence from the most recent UK wide Infant Feeding Survey shows that only 76% of women initiate breastfeeding and by 6 weeks after childbirth, only 48% are still breastfeeding [1]. Epidural analgesia provides the most effective pain relief for labour relative to other forms of analgesia, and is used by approximately one fifth of women giving birth in the UK [2, 3]. However, this efficacy comes at the cost of unwanted side effects including an increased rate of instrumental vaginal delivery, prolonged duration of labour (notably second stage) and an increased requirement for labour augmentation [4].

It is controversial whether intrapartum epidural analgesia has a negative impact on infant feeding. Two questions are central to this debate. First, does epidural pain relief per se influence breastfeeding? Some studies have suggested that it is associated with reduced breastfeeding initiation [5, 6] and earlier breastfeeding cessation [7] although others have found no association [8, 9]. The majority of evidence in favour of a negative effect of epidural analgesia on breastfeeding success is derived from non-randomised studies. Therefore, there is currently no strong evidence to confirm or refute an impact of epidurals.

Second, it has been suggested that fentanyl, an opioid widely used in ambulatory epidural pain relief, is

responsible for reducing breastfeeding initiation and duration [10]. It has previously been reported that the dose of epidural fentanyl received in labour is associated with bottle feeding at hospital discharge [11] and cessation of breastfeeding before 6 weeks postpartum [12]; however, only the latter finding was from a randomised study. Whilst it has been confirmed that fentanyl administered via the neuraxial route during labour undergoes maternal-fetal transfer, there is no evidence for a detectable impact on infant behaviour. In the absence of demonstrable fetal effects, another plausible explanation for a dose-dependent relationship has not been put forward.

The Comparative Obstetric Mobile Epidural Trial (COMET) demonstrated a reduced instrumental vaginal delivery rate with Combined Spinal Epidural (CSE) and Low-Dose Infusion (LDI), relative to a high-dose epidural technique, in nulliparous women, with no reduction in the efficacy of pain relief [13]. It has been suggested that a mobile technique should be offered to all women who request epidural pain relief in labour [14] and the recent UK NICE intrapartum care guideline recommends routine use of low-dose epidural regimens which require the inclusion of fentanyl to provide adequate pain relief [15]. It is therefore important to determine that such techniques do not adversely affect breastfeeding.

Data on breastfeeding initiation, and duration up to 12 months postpartum were collected as pre-defined secondary outcomes during the COMET trial comparing a bupivacaine only control and two mobile fentanyl techniques. Breastfeeding outcomes were also collected for a comparison group of nulliparae who did not receive epidural analgesia. The aim of the study was to examine the effect of epidurals *per se* and the use and dose of epidural fentanyl received during labour on breastfeeding initiation and duration.

## Methods

### Population and randomisation

The trial population included all nulliparous women who requested epidural pain relief for labour at two tertiary maternity units. Women were not eligible if they had a contraindication to epidural analgesia, had undergone a previous epidural or spinal procedure or had received pethidine for pain relief in the four preceding hours. All nulliparous women who planned to deliver at the trial centres were sent study information at 34 weeks gestation and further information was given by the duty anaesthetist prior to obtaining written consent.

Trial allocation, which included minimisation for age and ethnic group, was performed using a programme provided by a clinical trials unit and located on a dedicated computer on each delivery suite. Women were randomised

to receive high-dose epidural analgesia (Control) or one of two mobile epidural techniques, Combined Spinal Epidural (CSE) or Low Dose Infusion (LDI). Both mobile regimens utilised a low-dose mixture of bupivacaine and fentanyl whilst the control technique used bupivacaine alone. The epidural techniques to which women were randomised have been described in detail elsewhere [7]. A summary is included as an Appendix for reference. The study was approved by local research ethics committees.

### Non-epidural comparison group

A matched comparison group of women who did not receive regional analgesia during labour was recruited to establish the prevalence of backache (the primary long-term trial outcome) and other longer-term outcomes at 12 months following non-epidural delivery. The comparison group was selected by sequentially matching nulliparous women with non-epidural deliveries to each trial group recruit for mode of delivery and ethnicity as closely as possible. Women in the comparison group were informed about the study in the first 24 h following birth and underwent the same postpartum follow up as those randomised to the trial.

### Data collection and outcome measures

Obstetric and anaesthetic data were collected for the trial groups throughout labour and delivery by the duty anaesthetist and attending midwife. Baseline characteristics and delivery mode for the comparison group were obtained from hospital case notes. Women were interviewed by a research midwife 24–48 h after delivery, whilst in hospital, or at home in the rare event of very early discharge. For all study groups, women were asked in the interview whether they had already initiated breastfeeding and how long after birth this had occurred (0–30 min, < 1 h, 1–2 h, 2 or longer).

Long-term outcomes were obtained from a self-completed postal questionnaire at 12 months postpartum. Women were asked how long they had breastfed for (in months and weeks) and whether they were still breastfeeding at the time of completing the questionnaire.

### Sample size

Sample size calculations were made for the primary short and long-term outcome measures. Power calculations for mode of delivery (primary short term outcome) were based on data from a retrospective analysis of nulliparous women in a maternity unit where Combined Spinal Epidural (CSE) was first introduced as routine procedure. Detection of a change in spontaneous vaginal delivery from 50 to 65% with a power of 80% (1-beta) and 5% significance level (two sided alpha) required 180 women in each arm. The recruitment of a greater number of

women was dictated by the primary long term outcome, namely new backache [16]. The lower prevalence necessitated 314 women in each trial arm and accounting for anticipated loss to 12 month follow-up, it was decided to recruit 350 per arm.

**Analysis**

The proportion of women who breastfed was compared between epidural techniques and matched non-epidural comparisons (Chi-square). Women in the non-epidural comparison group were divided into those who had received pethidine for analgesia in labour (Non-epidural pethidine) and those who had used other forms of analgesia or none at all (Non-epidural no pethidine). It has been previously reported that maternal systemic opioids can delay the initiation of breastfeeding [17], thus the distinction in analysis was made to avoid heterogeneity in the non-epidural group.

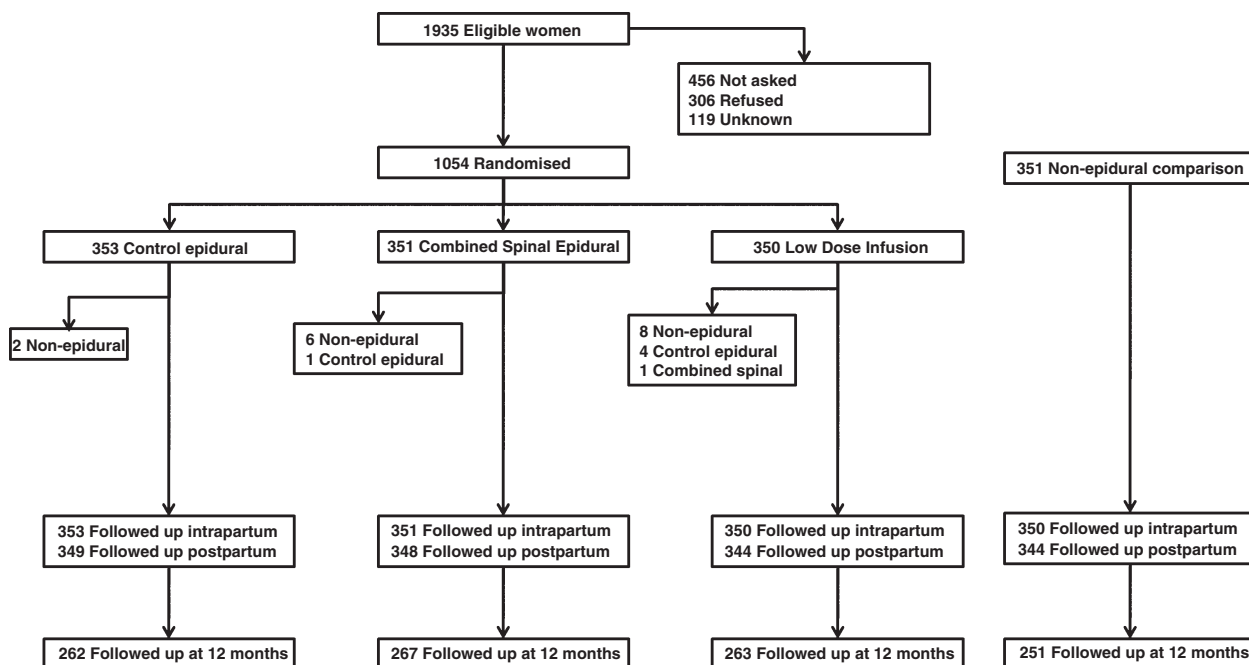
Statistical analysis was conducted with SPSS for Windows version 16 (© SPSS UK Ltd, Woking, Surrey UK). All trial analyses were conducted in adherence to an intention-to-treat methodology and main comparisons were between each trial group separately relative to Control. The duration of breastfeeding after birth, reported by women at 12 month follow up, was subjected to Kaplan-Meier analysis to generate a cumulative survival plot. Mean and median survival times were calculated according to trial group allocation and standard error and 95% confidence intervals calculated. Regression

analysis was performed including a number of relevant variables: study group (including epidural technique), fentanyl dose, delivery mode, maternal age and ethnicity to determine whether any of these factors were independently predictive of breastfeeding initiation. Odds ratios with 95% Confidence Intervals were calculated for each variable. All significance levels were set at  $p < 0.05$ .

**Results**

Of the 1054 women recruited to the trial, 353 were allocated to Control, 351 to CSE and 350 to LDI. The recruitment rate (24 h per day) was 55% of all potentially eligible women. Figure 1 shows progress through the trial. The commonest reason for non-recruitment of eligible women was not being asked to take part by the duty anaesthetist because of clinical workload. Baseline characteristics (Table 1) were similar across trial groups. Delivery mode (the primary short term trial outcome) and birthweight are also shown.

We recruited 351 women to the non-epidural comparison group (Fig. 1). Their characteristics are shown in Table 1 alongside women randomised to the trial. As anticipated, it was not always possible to match non-epidural comparisons to the trial groups for delivery mode, since regional anaesthesia is frequently used for Caesarean section and instrumental vaginal delivery. Table 1 shows that this was the main difference between non-epidural and epidural groups; there were fewer



**Figure 1** Progress of women through the trial, including non-epidural comparisons.

**Table 1** Baseline characteristics of trial participants and non-epidural comparison group.

	Control n = 353	CSE n = 351	LDI n = 350	Non- Epidural n = 351
Age; years n (%)				
≤ 19	52 (14.7)	49 (14.0)	52 (14.9)	65 (18.5)
20–24	78 (22.1)	80 (22.8)	78 (22.3)	81 (23.1)
25–29	109 (30.9)	107 (30.5)	108 (30.9)	105 (29.9)
30–34	82 (23.2)	83 (23.6)	79 (22.6)	73 (20.8)
≥ 35	32 (9.1)	32 (9.1)	33 (9.4)	26 (7.4)
NK	0	0	0	1 (0.3)
Ethnic group n (%)				
White	302 (85.6)	302 (86.0)	298 (85.1)	295 (84.1)
Asian	36 (10.2)	34 (9.7)	38 (10.9)	25 (7.1)
Other	15 (4.2)	15 (4.2)	14 (4.0)	18 (5.1)
NK	0	0	0	13 (3.7)
Induced labour n (%)	153 (43.3)	140 (39.9)	162 (46.3)	52 (15.3)
Weeks gestation n (%)				
≤ 37	27 (7.7)	24 (6.9)	25 (7.3)	NK
≥ 41	142 (40.2)	146 (41.6)	145 (41.4)	NK
Mode of delivery n (%)				
SVD	124 (35.1)	150 (42.7)	150 (42.9)	259 (73.8)
Instrumental	131 (37.1)	102 (29.1)	98 (28.0)	52 (14.8)
Caesarean section	98 (27.8)	99 (28.2)	102 (29.1)	30 (8.5)
Not recorded				10 (2.9)
Mean fentanyl dose µg (SD)				
First stage	NA	96.9 (53.7)	150.6 (93)	NA
Second stage	NA	10.4 (18.9)	12.2 (30.6)	NA

SD, Standard deviation; NK, Not known; NA, Not applicable.

Caesarean sections and instrumental deliveries in the non-epidural group. Of the 351 women in the comparison group, 151 (43%) received pethidine for analgesia during labour, with 200 women using other forms of analgesia (Entonox, TENS, water) or no analgesia.

### Postpartum infant feeding

Table 2 shows infant feeding patterns 24–48 h after delivery. A similar proportion of women in each epidural

trial group had initiated breastfeeding at this time. Women in the non-epidural (no pethidine) comparison group reported similar rates of breastfeeding initiation to those who had received epidural analgesia. Significantly fewer women in the non-epidural, pethidine comparison group reported initiation of breastfeeding relative to all epidural groups ( $p = 0.002$  vs Control) and the non-epidural, no-pethidine group ( $p = 0.035$ ). No differences were found between groups in the time of first initiation. Table 3 shows the regression analysis to identify factors which were independently predictive of breastfeeding initiation. Women in older age and non-white ethnic groups were more likely to initiate breastfeeding. Delivery mode, study group allocation (including epidural techniques and both non-epidural groups) and epidural fentanyl dose were not predictive.

### Follow up at 12 months and breastfeeding duration

Response rate to the postal questionnaire at 12 months after birth was 78% in each trial group, but significantly lower, at 73%, in the non-epidural comparison group. The baseline characteristics of women who were followed up are given in Table 4. As previously described, non-epidural group characteristics reflect the different distribution of mode of delivery resulting from their method of recruitment relative to those randomised to the trial.

Figure 2 shows the duration of breastfeeding expressed as cumulative survival in weeks after delivery and estimated mean duration of breastfeeding in weeks for each study group is presented in Table 5. Mean duration was greatest in the non-epidural, no pethidine comparison group, but the difference was not statistically significant. Mean breastfeeding times for women in the epidural control group and non-epidural, pethidine comparison group were similar. Women in the two mobile epidural techniques had slightly greater mean breastfeeding duration when compared to control but

	Control n = 353	CSE n = 351	LDI n = 350	Non-epidural comparison n = 351	
Followed up	349	348	344	351	
				No pethidine 200	Pethidine 151
Initiated breastfeeding n (%)	231 (66.2)	230 (66.1)	217 (63.1)	132 (66.0)	84 (55.6)*†
Time to breast from delivery n (%)					
< 30 min	42 (12.0)	53 (15.2)	45 (13.1)	35 (17.5)	21 (13.9)
< 1 h	49 (14.0)	44 (12.6)	43 (12.5)	29 (14.5)	25 (16.6)
1–2 h	76 (21.8)	55 (15.8)	63 (18.3)	27 (13.5)	20 (13.2)
> 2 h	64 (18.3)	78 (22.4)	67 (19.5)	42 (21.0)	18 (11.9)

\*Significance  $p = 0.002$  vs Control.

†Significance  $p = 0.035$  vs Non-epidural comparison (no pethidine).

CSE, combined spinal epidural; LDI, low dose infusion.

**Table 2** Infant feeding by study group (post-delivery interview).

**Table 3** Logistic regression analysis of variables associated with breastfeeding initiation.

Variable	Total	Odds ratio	95% CI	p Value
<b>Ethnicity</b>				
White	1197	1.0*	Reference	
Black	44	3.63	(1.17–11.27)	0.026
Asian	133	1.94	(1.09–3.44)	0.024
Other	18	1.33	(0.31–5.68)	0.701
<b>Study group</b>				
Control	353	1.0*	Reference	
CSE	351	0.85	(0.57–1.26)	0.415
LDI	350	0.85	(0.57–1.26)	0.416
Comp (no pethidine)	200	1.20	(0.73–1.97)	0.465
Comp (pethidine)	151	0.85	(0.50–1.46)	0.561
<b>Delivery mode</b>				
Spontaneous	683	1.0*	Reference	
Ventouse	227	0.86	(0.57–1.28)	0.448
Forceps	135	1.15	(0.70–1.89)	0.574
Rotn. forceps	21	1.29	(0.41–4.1)	0.665
C-section	329	1.03	(0.70–1.52)	0.868
<b>Age; years</b>				
< 19	218	1.0*	Reference	
20–24	317	1.67	(1.02–2.74)	0.044
25–29	429	4.53	(2.83–7.26)	< 0.001
30–34	317	5.09	(3.10–8.35)	< 0.001
35–39	103	8.89	(4.44–17.80)	< 0.001
> 40	20	11.61	(2.48–54.28)	0.002
<b>Fentanyl dose; µg</b>				
0	648	1.0*	Reference	
1–100	316	0.77	(0.47–1.39)	0.386
101–200	288	0.56	(0.28–1.13)	0.106
201–300	112	0.54	(0.24–1.21)	0.135
301–400	31	1.36	(0.35–5.25)	0.655
> 401	10	0.52	(0.11–2.38)	0.395

\*Reference values.  
CSE, combined spinal epidural; LDI, low dose infusion.

again with overlapping confidence intervals, so this difference was not statistically significant. The overall mean breastfeeding survival time was 15.05 weeks (standard error 0.53 weeks) with 95% CI: 14.01–16.09. There was no difference in the small proportions of women still breastfeeding at 12 months between the study groups.

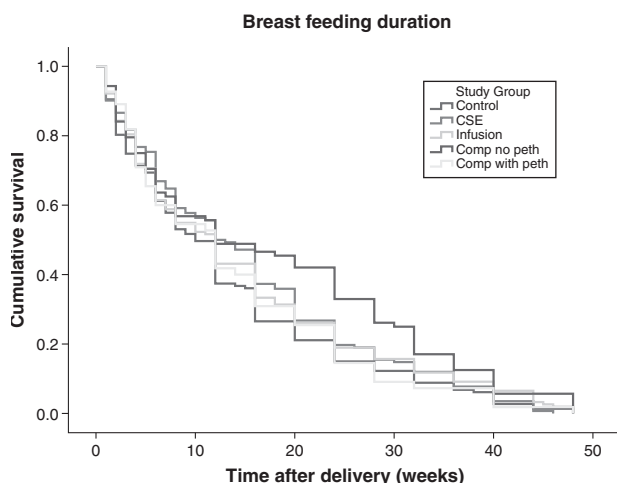
**Discussion**

The benefits of breastfeeding to infants and mothers are now uncontroversial. Breast fed babies derive protection against infection and are less likely to subsequently develop hypertension, hypercholesterolaemia and obesity [18, 19]. Maternal benefits include a greater likelihood of returning to their pre-pregnancy weight and protection against breast and ovarian cancers [20]. UK Health departments have set targets to increase breastfeeding initiation by 2% year on year. Thus, the investigation of any interventions that might reduce the likelihood of breastfeeding initiation must be accorded high priority.

**Table 4** Baseline characteristics of respondents to 12 month follow up questionnaire.

	Control n = 262	CSE n = 266	LDI n = 262	Non-epidural n = 251
<b>Age; years n (%)</b>				
≤ 19	23 (8.9)	28 (10.5)	31 (11.8)	30 (11.7)
20–24	53 (20.2)	57 (21.4)	48 (18.3)	40 (15.6)
25–29	84 (32.1)	82 (30.8)	91 (34.7)	79 (30.9)
30–34	72 (27.5)	67 (25.2)	63 (24.0)	59 (23.0)
≥ 35	30 (11.5)	32 (12.0)	29 (11.1)	18 (7.0)
NK	0 (0)	0 (0)	0 (0)	10 (11.7)
<b>Ethnic group n (%)</b>				
White	235 (89.7)	232 (87.2)	233 (88.9)	218 (86.9)
Asian	21 (8.0)	22 (8.3)	21 (8.0)	17 (6.8)
Other	6 (2.3)	12 (4.5)	8 (3.1)	8 (3.2)
NK				8 (3.2)
Induced labour	120 (45.8)	110 (41.4)	131 (50.0)	34 (13.5)
<b>Weeks gestation</b>				
≤ 37	15 (5.7)	15 (5.6)	21 (8.0)	NK
≥ 41	110 (42.0)	114 (42.9)	110 (42.0)	NK
<b>Mode of delivery</b>				
Spontaneous vaginal	88 (33.6)	109 (41.0)	113 (43.1)	189 (75.3)
Instrumental	109 (41.6)	77 (28.9)	77 (29.4)	37 (14.7)
Caesarean section	65 (24.8)	80 (30.1)	72 (27.5)	19 (7.6)
NK	0	0	0	6 (2.4)

NK, Not known; CSE, combined spinal epidural; LDI, low dose infusion.



**Figure 2** Breastfeeding duration reported at 12 months. Presented as cumulative survival plot of breastfeeding duration in the year following birth.

Limitations in the design of previous studies have ensured that the potential relationship between epidural analgesia and breastfeeding remains controversial [21]. Heterogeneous systemic and epidural analgesia regimens and the potential for selection bias resulting from non-randomised assignment of pain relief, reduce the validity of any findings. A recent cohort study by Torvaldsen et al. reported an association between epidural and early

	Control <i>n</i> = 353	CSE <i>n</i> = 351	LDI <i>n</i> = 350	Non-epidural <i>n</i> = 351	
Followed up	262	267	263	251	
				No pethidine 150	Pethidine 101
Breastfeeding duration; weeks					
Estimated mean	13.34	15.51	14.98	18.01	13.93
95% CI	11.41–15.27	13.47–17.54	12.90–17.06	14.93–21.10	10.82–17.03
Standard error	0.98	1.04	1.06	1.56	1.58
Still breastfeeding at 12 months <i>n</i> (%)					
	17 (6.5)	21 (7.9)	10 (3.8)	10 (6.7)	4 (4.0)

**Table 5** Breastfeeding duration after birth by study group (12 month postpartum questionnaire).

CSE, combined spinal epidural; LDI, low dose infusion.

cessation of breastfeeding [22]. However, epidural techniques were not standardised with no distinction made in analysis, even between women who received epidural analgesia in labour and those who required spinal anaesthesia for Caesarean section. Intrathecal and epidural fentanyl doses utilised in these distinct techniques differ by an order of magnitude. Such heterogeneity of techniques confounds meaningful interpretation and must be set in the context of several investigations which have failed to identify any adverse effect on breastfeeding up to 6 weeks postpartum [23, 24].

The only previous randomised controlled trial was small and included only women who had previously breast-fed. It compared three different epidural doses of fentanyl during labour and showed no significant difference in breastfeeding difficulty at 24 h after delivery but reported an association between epidural fentanyl dose and breastfeeding cessation before 6 weeks [12]. A plausible mechanism for a fentanyl effect on late breastfeeding patterns has yet to be proposed. Fentanyl is a highly lipid soluble opioid which easily crosses the placenta. Studies of maternal–fetal transfer by assay of umbilical vessel samples have confirmed that fentanyl is detectable in fetal blood at the time of delivery. However, no consistent effect on neonatal neurobehavioral scores, which could account for an effect on breastfeeding, is demonstrable [25]. The kinetics of fentanyl redistribution and metabolism are well characterised and elimination from the maternal circulation occurs over several hours following epidural administration. To postulate an effect on early breastfeeding cessation some weeks after delivery, especially in the absence of an impact immediately postpartum, seems to stretch plausibility.

There is little debate about the enhanced analgesic efficacy of combination opioid and local anaesthetic epidural solutions for the provision of mobile epidural analgesia in labour. The use of epidural fentanyl is ubiquitous in current UK epidural practice. Thus, the COMET study provided an opportunity to examine the evidence for an effect of fentanyl by direct

randomised comparison of techniques with and without opioid in a manner that would now, arguably, not be possible. With reference to the two questions outlined in the introduction, our study provides robust trial evidence to reject a fentanyl effect, since breastfeeding patterns between the epidural groups were similar. Women in the bupivacaine only control epidural group did not receive fentanyl and even in the Low-Dose Infusion group, where the largest doses of fentanyl were administered (mean 179.5 µg, SD 98.4), we found no evidence that fentanyl exerted an influence on initiation or duration of breastfeeding. This randomised finding is supported by logistic regression analysis which did not identify fentanyl dose as a variable independently predictive of breastfeeding initiation.

Women who received no epidural analgesia did not demonstrate higher rates of breast feeding initiation than those in the epidural groups. Indeed, there were lower initiation rates in the non-epidural group who had systemic administration of pethidine, although multivariate analysis did not show study group to be predictive of breastfeeding initiation, identifying maternal age and ethnicity as the only independently associated factors. Given that inclusion in the non-epidural comparison group was determined by non-randomised matched selection and use of pethidine, a matter of maternal choice, conclusions from the multivariate analysis must be regarded as the more robust. However, although the study does not demonstrate pethidine to be independently predictive of reduced initiation, there was no evidence at all of increased breastfeeding initiation rates among women who had no epidural.

Pethidine is a lipophilic opioid which undergoes fetal transfer after maternal intramuscular administration. It has prolonged activity in the maternal circulation ( $\beta$  half-time = 180–264 min) and is metabolised to an active metabolite, nor-pethidine. The potential for adverse neonatal effects of maternal systemic opioids have been previously reported [26] and account, in part, for the popularity of epidural analgesia which provides highly

effective pain relief without sedation of mother or infant. In the study by Torvaldsen considered above, all women in the epidural group who delivered vaginally uniformly received systemic pethidine prior to epidural pain relief. Teasing out the effect of epidural opioids alone with such analgesic heterogeneity is arguably not possible. A minimum time period of 4 h after pethidine administration, preceding epidural insertion, was a pre-condition for eligibility in COMET. The trial population can therefore be regarded as one which would model any epidural fentanyl effect with high fidelity.

Our analysis showed that women randomised to mobile epidural techniques did not cease breastfeeding early but breastfed slightly longer than those women in the control arm of the study, although not significantly so. These data add weight to the argument *against* a fentanyl effect since one would expect epidural techniques utilising higher dose opioids to be associated with earlier breastfeeding cessation. Moreover, the pattern of breastfeeding cessation in women in the non-epidural, pethidine group was similar to epidural control. Kaplan-Meier analysis revealed that women in the non-epidural, no pethidine group breast feed for longer than their trial or comparison group counterparts; however, this again was not statistically significant. It is feasible that women who choose not to receive epidural or opioid pain relief during childbirth represent a population who are more likely to breast feed for longer after birth; however, our data cannot be used to support such an assertion.

Our data set demonstrated factors independently predictive of breastfeeding initiation which are consistent with the literature, notably maternal age and ethnicity, although we did not find a positive association with spontaneous vaginal delivery which has been previously described [7].

There are limitations to our study. Sample size estimates were not determined by breastfeeding initiation or duration; however, these outcomes were pre-specified prior to trial commencement and our sample size is amongst the largest examined by any methodology for evidence of an effect of epidurals on breastfeeding. Maternal reports of breastfeeding at postpartum interview may not accurately reflect successful initiation and our data on breastfeeding duration are derived from a self-administered questionnaire. We did not collect data on additional lactation support available to women in the study; however, we have no reason to expect an imbalance across trial arms of this or other variables, known to influence breastfeeding. Our main conclusions are drawn from analysis of pre-defined secondary outcomes of a large randomised trial and thus as rigorous as any currently in this field.

The benefits of breastfeeding to women and their children are well established. As key health professionals

during labour and delivery, anaesthetists have a responsibility to investigate interventions which may adversely affect breastfeeding rates. Our study is the first randomised controlled trial to conclusively refute a negative effect of the inclusion of fentanyl in epidural solutions and our findings do not support the hypothesis that epidural analgesia *per se* has an effect on breastfeeding initiation.

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### Appendix: epidural techniques

All women received a 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) using a midline approach with loss of resistance to air or saline. Mobile techniques used a low dose mixture of bupivacaine 0.1% (1 mg.ml<sup>-1</sup>) with fentanyl 2 µg.ml<sup>-1</sup>.

### Control group

Following a test dose of 3 ml lidocaine 2% (60 mg), analgesia was initiated with 10 ml bupivacaine 0.25% (25 mg). Doses of 10 ml bupivacaine 0.25% (25 mg) were provided on maternal request for pain relief, but no more than hourly.

### Combined spinal epidural (CSE)

Analgesia was established by subarachnoid injection, via a 120 mm, 24-gauge Sprotte<sup>®</sup> needle (Pajunk, Medizin-technologie, Geisingen, Germany), of 1 ml bupivacaine 0.25% (2.5 mg) and 25 µg fentanyl using a needle-through-needle method at a single spinal interspace. As spinal analgesia receded, epidural analgesia was initiated by 15 ml of low dose mixture (bupivacaine 15 mg, fentanyl 30 µg). Subsequent analgesia was given by bolus of 10 ml low dose mixture. To minimise the risk of post dural puncture headache, only one attempt at intrathecal injection was permitted in the CSE protocol. If the spinal failed, epidural block was established with 15 ml of low dose mixture (bupivacaine 15 mg, fentanyl 30 µg).



**Low dose infusion (LDI)**

Analgesia was established with of 15 ml of low dose mixture (bupivacaine 15 mg, fentanyl 30 µg). A fixed rate infusion of low dose mixture at  $10 \text{ ml.h}^{-1}$  was commenced via a portable Baxter AP2 Pump<sup>®</sup> (Baxter, Deerfield, IL 60015-4625, USA). Inadequate pain relief was treated with 10 ml low dose mixture on maternal request, but no more than hourly. The infusion was discontinued at the end of the third stage of labour or at operative delivery.

No epidural test dose was given in mobile techniques to avoid motor blockade. Inadequate pain relief in the Control group was treated with epidural fentanyl 50 µg and/or more concentrated bupivacaine solutions (bupivacaine 0.375 or 0.5%). Rescue analgesia in each mobile group comprised a 10 ml bolus of the low dose mixture. If inadequate analgesia persisted, 5–10 ml bupivacaine 0.25% was administered.