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The Comparative Obstetric Mobile Epidural Trial (C.O.M.E.T.) Ambulatory Epidural Analgesia, Delivery Mode And Pain Relief: A Randomised Controlled Trial.

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Epidural analgesia for labour is associated with increased obstetric intervention (1). Ambulatory techniques may increase the rate of spontaneous vaginal delivery. We will present a randomised controlled trial investigating the effect of ambulatory epidural analgesia on mode of delivery.

2100 primiparous women, requesting epidural analgesia, were randomised to receive intermittent boluses of 0.25% bupivacaine, combined spinal epidural or low-dose infusion, each using 0.1% bupivacaine with fentanyl 2mcg/ml. Intrapartum data collection included mode of delivery, visual analogue pain scores and mobility assessment. All women were given a prenatal questionnaire and were interviewed post-delivery to assess pain relief and maternal satisfaction. Long term outcomes (not presented) are being assessed at 12-month follow-up.

A computer randomisation error led to recruitment of 1054 women with an unequal age distribution (C.O.M.E.T. 1). A second data set of 1050 subjects, with an equal age distribution, was therefore recruited (C.O.M.E.T. 2). Results will be presented for C.O.M.E.T. 2 alone as the primary data, and for the combined data sets using age standardisation.

We will report whether either ambulatory technique is associated with any significant difference in the incidence of spontaneous vaginal delivery. The rates of instrumental vaginal delivery and emergency caesarean section along with efficacy of analgesia for each technique will also be reported.

References

1) The Cochrane Library, Issue 4, 1999.

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Title - A Multi Center Study of the Effects of Analgesia on the Progress Of Labor
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Introduction - The association between use of epidural analgesia and cesarean section for dystocia has been the focus of much study. One problem repeatedly seen has been the lack of a clear definition and management for dystocia and consistency in obstetric practice.^{1,2} The purpose of this multi center, multidisciplinary, prospective, randomized, controlled study is to compare 2 analgesic methods on delivery outcome with strict definitions of dystocia plus protocol driven obstetric management of labor.

Method - Following IRB approval and informed consent, healthy, nulliparous, women in spontaneous labor, requesting analgesia were randomized to receive patient controlled epidural analgesia -PCEA (0.08% bupivacaine + 1.67 mcg/ml fentanyl) or intravenous patient controlled analgesia - IVPCA (fentanyl). Patients were excluded from the study if any patient or obstetric condition existed known to increase the incidence of operative delivery. Both the analgesic and obstetric management of the first and second stages of labor were protocol-driven. Strict criteria for diagnosis and management of dystocia, were developed and enforced by the obstetrical consultants. Data collection was extensive, with variables (including VAS pain, motor and sensory block, cervical dilation, temperature, sedation score and use of oxytocin), audited every 2 hours during first and every 30 minutes during second stages of labor. The duration of labor, mode of delivery and reasons for intervention were collected. Data was analyzed on an intention to treat basis.

Results - Four Canadian hospitals participated in the data collection. To date data from 185 patients has been analyzed, with 88 randomized to IVPCA and 97 to PCEA. The demographic data, including age, height, weight, initial cervical dilation and fetal weight, were similar. The results of primary outcome are as follows:

	PCA (n = 88)	PCEA (n=97)
C/S - all	9 (10.2%) p=ns	11 (11.3%) p=ns
C/S for dystocia	5 p=ns	3 p=ns
C/S - dystocia- first/second stage	2 / 3 p=ns	2 / 1 p=ns

Discussion - In this strictly controlled randomized study we have not demonstrated any difference in the need for cesarean section between our 2 analgesic methods.

References - 1.AmJObstetGynecol 1993;169:851. 2. Anesthesiology 1997;87:487.

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A randomized Trial of Patient-Controlled Epidural Versus Patient-Controlled Intravenous Analgesia During Labor
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Our purpose in this ongoing study is to evaluate the effects of patient-controlled epidural analgesia (PCEA) vs patient-controlled intravenous analgesia (PCIA) on the course of labor and delivery.

Following IRB approved consent, healthy nulliparous women with term singleton cephalic gestations in spontaneous labor obstetrically managed in a codified manner, were randomized to either PCEA or PCIA at complaint of pain. Following a 0.25% bupivacaine and fentanyl bolus, PCEA was maintained with 0.0625% bupivacaine and fentanyl 2 mcg/ml at 5 ml/h with 3 ml boluses every 15 minutes as needed. Following a 50 mg meperidine bolus, PCIA was maintained with 15 mg every 10 minutes as needed. Data were analyzed on an intent-to-treat basis using Student's t-test and chi-square test.

At the time of this analysis 342 women were randomized: 170 to PCEA and 172 to PCIA. Seven percent women who received PCIA crossed over to PCEA due to inadequate pain relief. Demographics including gestational age and cervical dilatation at initiation of analgesia were similar in both groups. The overall cesarean delivery rate was similar in both groups using intent-to-treat analysis (6.5% vs 8.7%, PCEA vs PCIA, NS) and protocol compliant analysis. Forceps deliveries were increased with epidural analgesia (13% versus 3%, P = 0.001). With PCIA though, more neonates required naloxone (6% vs 0%, P = 0.001), and had a lower umbilical arterial pH (7.22 0.07 vs 7.25 0.07, P < 0.001). However, Apgar scores < 5 at 1 min and < 7 at 5 min, and NICU admissions were similar in both groups. Epidural analgesia was associated with maternal fever (33% versus 7% P < 0.001), oxytocin augmentation of labor (48% versus 34% P < 0.05), and hypotension after analgesia. Women who received PCEA reported better analgesia satisfaction scores during labor and delivery compared to women who received PCIA .

In women receiving PCEA versus PCIA, cesarean deliveries are not increased, although forceps deliveries are increased. Transient neonatal depression though is increased with PCIA.

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0.075% Epidural Ropivacaine And Bupivacaine Are Clinically Indistinguishable For Labor Analgesia

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Introduction: At ED₅₀ concentrations, ropivacaine (Rop) is 40% less potent than bupivacaine (Bup).¹ However, when higher concentrations are used for PCEA labor analgesia, these drugs appear equipotent.^{2,3} We designed a PCEA study comparing dilute concentrations of Rop and Bup to detect clinically relevant differences in potency between the drugs.

Methods: Following IRB approval and written informed consent, 42 ASA class I/II nulliparous patients in active labor were randomized to receive 0.075% Rop or Bup, each with 2 µg/ml of fentanyl. The PCEA settings were: basal rate 6 ml/hr, bolus 5 ml, lockout 10 min. For inadequate analgesia, patients received 10ml of the study solution. Pain relief, motor and sensory block, drug volumes, duration of labor, mode of delivery and patient satisfaction were assessed.

Results: There were no differences in patient demographic data, maximum sensory levels, labor duration, or delivery mode. The hourly drug volumes, pain scores, and motor block are shown below. All patients reported good or excellent pain relief.

	Total Drug Used (ml/hr)	% Bromage 1		Average VAS (0-10)	
		30min	180min	30min	180min
Rop (n=20)	15.5 ± 2.8	30	22	1.1 ± 0.4	0.7 ± 1.93
Bup (n=22)	14.4 ± 3.9	23	14	1.3 ± 0.5	1.8 ± 2.32

Conclusion: Similar to previous studies using patient-controlled techniques at higher concentrations,^{1,2} 0.075% Rop and Bup produce indistinguishable labor analgesia and are clinically equipotent. This is in contrast to studies of analgesic potency in which an ED₅₀ value is isolated using an up-down patient allocation technique.

References:

1) Anesthesiology 1999;90:944-50 2) Anesthesia & Analgesia 1998;86:527-31 3) Anesthesiology 1998; 89(3A):A1023.