Combined Spinal-Epidural Analgesia and Epidural Analgesia in Labor: Effect of Intrathecal Fentanyl vs. Epidural Bupivacaine as a Bolus

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Objective: *To compare the clinical effects of intrathecal fentanyl with conventional epidural bupivacaine bolus before the same continuous epidural infusion for labor analgesia.*
Material and Method: *Fifty parturients in active labor were randomized to receive subarachnoid fentanyl 25 mcg as part of a combined spinal epidural analgesia (CSE) or bupivacaine 0.25% 10 ml incrementally into the epidural space in the epidural group. After that, 0.0625% bupivacaine with fentanyl 2 mcg/ml was infused via epidural catheter in all women at a rate of 12 ml/h. Verbal numeric pain scores (VNPS), onset time to pain relief, times of additional analgesia and other side effects were recorded.*
Results: *Mean (SD) onset time to the first pain free contraction was not significantly different (7.8 $\pm$ 4.3 min in the CSE group, 10.2 $\pm$ 5.1 min in epidural group, $p = 0.085$). Most of the patients in the CSE group required additional epidural bolus dose (80% compared to 48% in the Epidural group, $p = 0.038$). There was no difference in motor blockage at time of delivery or mode of delivery. Significantly more women in the CSE group had pruritus (68%VS none in the epidural group, $p < 0.001$), all had mild degree and did not require any treatment. There was no difference in other side effects.*
Conclusion: *Intrathecal fentanyl as part of CSE did not produce statistically a significant faster onset compared to epidural bupivacaine bolus. Most of the patients in the CSE group required epidural bolus after intrathecal fentanyl with a higher incidence of pruritus.*

Keywords: *Combined spinal epidural analgesia, CSE, Epidural analgesia, Labor, Obstetric*

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Labor pain is described as excruciating and a significant contributor to stress and anxiety by many patients. Several techniques have been developed to alleviate this pain while minimizing effects on the mother, the fetus, and the progression of labor. In Thailand, epidural analgesia is accepted as the most effective method to relieve labor pain. However, some studies reported that epidural analgesia might prolong labor in nulliparous and increase the incidence of instrumental vaginal delivery, especially if administered early in labor[1,2]. Combined spinal-epidural analgesia (CSE) involves injection of a small dose of local anesthetic and/or opioid into the subarachnoid space in order to initiate analgesia, followed by bolus or continuous injection via the epidural catheter. This technique has become increasingly popular in many countries because of its rapid onset with a small initial dose. This initial dose reduces subsequent requirement of epidural analgesia and preserved the ability to walk late in labor[3-5]. However, it is more complicated, expensive and associated with an increased incidence of nausea, vomiting, hypotension and pruritus[6,7].

The authors performed this prospective, randomized single-blinded control study to compare the effectiveness of CSE technique with the epidural technique for painless labor. The primary outcome

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studied was the onset of effective analgesia. The secondary outcomes included motor blockade at the time of delivery, mode of delivery and side effects.

Material and Method

The research ethics committee, Faculty of Medicine, Chulalongkorn University approved the protocol. Written informed consent was obtained from each parturient before the present study. Fifty healthy full-term pregnant women who were experiencing contraction at least once every 5 min who requested labor analgesia at King Chulalongkorn Memorial Hospital were enrolled in this prospective, randomized study. All complicated pregnancies such as twins, placenta previa, pregnancy-induced hypertension or the patient who has contraindication for regional analgesia were excluded from the present study.

Parturients were divided into two groups by using a sealed-envelope randomized technique. The CSE group (n = 25) underwent combined spinal-epidural analgesia. After skin local infiltration at L2-3 or L3-4 level, spinal analgesia was performed with a Quincke needle 27G. When the flow of cerebral spinal fluid was confirmed, fentanyl 25 mcg was given. Then the epidural space was identified with loss of resistance technique by a Tuohy needle 18G at the same level. This was followed by placement of a 20G epidural catheter, 3 cm into the epidural space. After a negative aspiration (no blood or cerebrospinal fluid from the epidural catheter after aspiration) and test dose by 0.25% bupivacaine 3 ml through the epidural catheter, an epidural infusion of 0.0625% bupivacaine with fentanyl 2mcg/ml was started at a rate of 12 ml/h.

In the epidural group (n = 25), the epidural block was performed with the same technique as above after local skin infiltration at L2-3 or L3-4 level. After a negative aspiration, 3 ml 0.25% bupivacaine was administered as a test dose, followed by 7 ml 0.25% bupivacaine incrementally. Then 0.0625% bupivacaine with fentanyl 2mcg/ml was continuously infused at a rate of 12 ml/h.

At the beginning, intravenous fluid was started and routine monitoring including the verbal numeric pain score (0-10) was recorded in all parturients. The authors performed the block in the lateral decubitus position. The patient was then positioned supine and remained in bed after this neuraxial block. Blood pressure (BP) and pain score were measured. The time when the pain score was less than 5 and the patient was satisfied with her pain relief was recorded. If the pain score was more than 5 after 20 minutes of the initial analgesia, 0.25% bupivacaine 10 ml in a divided dose was then administered via epidural catheter as a rescue drug. All the bolus medications were given carefully after a negative aspiration. The patient was monitored closely for the symptom of intrathecal bupivacaine injection by checking the level of analgesia and motor blockage. The intravascular injection was also monitored by asking if she felt dizzy, had tinnitus or had a metallic taste in her mouth.

The degree of motor block in the lower extremities was assessed with the modified Bromage scale (0 = no motor block; 1 = unable to raise extended leg, able to move knees and foot; 2 = unable to raise extended leg or knees, able to move foot; 3 = complete motor block of lower limb). Assessment of maternal BP, pain score (0-10), Bromage score (0-3), pruritus (none, mild, moderate or severe), shivering (none, mild, moderate or severe), and nausea (none, mild, moderate or severe) were made hourly. Hypotension was defined as decreasing more than 20% of systolic BP compared to the baseline before a neuraxial block. Fetal heart rate was monitored periodically. Obstetric residents and labor nurses, who were unaware of the anesthetic administration, managed labors according to the standardized protocols. Anesthesia duration was the time from the first neuraxial drug injection until delivery. Birth weight and APGAR scores were also recorded.

Statistics

Data is presented as mean $\pm$ standard deviation (SD), median (range) or number (%). Continuous, parametric data was compared using a student unpaired t-test. Continuous, non-parametric and rank data were compared using the Mann Whitney U test. Nominal data was compared using the Fisher exact test. A p-valve of < 0.05 was taken as a statistical significance.

From a pilot study, the mean $\pm$ SD onset time of the epidural analgesia was 12 ± 4.97 and the CSE group was 8.6 ± 2.1. For an overall type I error of 5%, fifteen parturients per group provided 80% power under this circumstance.

Results

Of the 50 eligible parturients for the present study, 25 parturients were randomly allocated in the CSE group and 25 parturients were in the epidural group. The two groups were similar in age, height, weight, parity, gestation, cervical dilatation, oxytocin requirement and pain score at the time of initiation of analgesia. (Table 1) There was no difference in speed of onset between the two groups (7.8 ± 4.3min in the

Table 1. Patient characteristics in the CSE and Epidural group

	CSE (n = 25)	Epidural (n = 25)
Age (yr)	25.9±5.5	26.3± 6.4
Height (cm)	156.4±5.26	158.4± 5.6
Weight (kg)	63.3±8.8	65.1± 9.2
Nulliparous (n)	16 (64%)	16 (64%)
Gestation (wk)	39.3±1.1	39.3± 0.75
Cervical dilation at induction of analgesia (cm)	5.04±1.1	5.4± 1.1
Receiving oxytocin during labor (n)	12 (48%)	13 (52%)
Pain score before anesthesia (0-10)	10 (5)	10 (4)

Value shown as mean ± SD, median (range) or number (%)

CSE group and 10.2 ± 5.1min in the epidural group, p = 0.085). The duration of anesthesia was not significantly different (225.6 ± 122.0 min in the CSE group and 204.9 ± 117 min in the epidural group, p = 0.542). However, most of the patients in the CSE group required an additional bolus medication to relieve their pain (80% in the CSE group vs. 48% in the epidural group, p = 0.038). There was no difference in the Bromage score at the time of delivery or the mode of delivery (Table 2). There was no statistical significant difference in birth weight or APGAR scores. All of the patients who had cesarean section had a Bromage score of 3 since it was recorded at the time of delivery, after additional anesthesia for cesarean section was given. The incidence of cesarean section was 16% in the CSE group and 16% in the epidural group (p = 1.00). The incidence of operative vaginal delivery was 40% in the CSE group and 48% in the epidural group. The most common indication of operative vaginal delivery was for prophylaxis. The reasons for cesarean section and operative vaginal delivery were described in Table 3 and 4.

For the side effects, the incidence of hypotension, shivering and nausea was low and not different between the groups. Patients in the CSE group had significantly more pruritus than the epidural group (68% vs. 0%, p < 0.001). However, all had mild symptoms and did not require any treatment. In the present study, none of the patients developed fetal bradycardia, migration or displacement of the epidural catheter, postdural puncture headache or other complications as above.

Discussion

Combined spinal-epidural analgesia for labor has become popular because of its combined advantage of spinal and epidural analgesia. These include faster onset, more reliable due to spinal component, minimal motor and sensory blockade, improved mobilization with higher mother satisfaction[3-5,8-10].

In the present study, the authors found that intrathecal fentanyl 25 mcg relieved labor pain within 7.8 min, which was comparable to the study by Palmer et al[7]. However, this is not significantly different statistically from the patients receiving 0.25% bupivacaine 10 ml into the epidural space for labor which relieved

Table 2. Onset and obstetrical outcome in the CSE and Epidural group

	CSE (n = 25)	Epidural (n = 25)	p-value
Time to pain relief (min)	7.8±4.3	10.2± 5.1	0.085
Anesthesia duration (min)	225.6±122	204.9± 117	0.542
Requested additional medication (n)	20 (80%)	15 (48%)	0.038
Bromage score at time of delivery (0-3)	0.5(3)	0 (3)	0.185
Pain score at time of delivery (0-10)	0 (10)	0 (5)	0.102
Mode of delivery			
Spontaneous vaginal (n)	11 (44%)	9 (36%)	0.725
Operative vaginal (n)	10 (40%)	12 (48%)	0.505
Cesarean (n)	4 (16%)	4 (16%)	1.000
Birth weight (gm)	3053±426	3220±393	0.156

Data shown as mean ± SD, median(range) or number (%)
No significant difference between CSE vs epidural (p > 0.05)

Table 3. Indication for cesarean section in the CSE and Epidural group (intent to treat)

	CSE (n = 25)			Epidural (n = 25)		
	All	Nulliparous	Parous	All	Nulliparous	Parous
Dystocia	2	2	0	4	3	1
Prolong 2nd stage	1	0	1	0	0	0
Thick meconium	1	1	0	0	0	0
Total	4/25 (16%)	3/25 (12%)	1/25 (4%)	4/25 (16%)	3/25 (12%)	1/25 (4%)

Table 4. Indication for operative vaginal delivery in the CSE and Epidural group (intent to treat)

	CSE (n=25)			Epidural (n=25)		
	All	Nulliparous	Parous	All	Nulliparous	Parous
Prophylaxis	8	6	2	7	6	1
Prolong 2nd stage	1	1	0	3	3	0
Late deceleration	0	0	0	1	0	1
Fetal distress	1	1	0	1	1	0
Total	10/25 (40%)	8/25 (32%)	2/25 (8%)	12/25 (48%)	10/25 (40%)	2/25 (8%)

Table 5. Complications in the CSE and Epidural group

	CSE (n = 25)	Epidural (n = 25)	p-value
Hypotension	2 (8%)	2 (8%)	1.000
Pruritus	17 (68%)	0 (0%)	<0.001
Shivering	5 (20%)	5 (20%)	1.000
Nausea/vomiting	2 (8%)	0 (0%)	0.49

Data shown as number (%)

the pain in 10 min. A previous study by Palmer et al, reported the mean onset time of 2.5 min by adding bupivacaine 2.5 mg together with fentanyl 25 mcg intrathecally[11]. A meta-analysis of all available data may finally answer the question of the speed of onset.

Even though the onset time of the CSE technique was not statistically different, there are certain situations where CSE may be the preferred technique. Spinal analgesia is easier to perform and more reliable in patients with severe pain. The epidural catheter can be placed easily after the patient has calmed down and cooperated. These also decrease the chance of accidental dural puncture.

None of the patients in the present study developed post dural puncture headache (PDPH). Collins et al[5] reported an incidence of PDPH of 2.3% in their series of 300 CSE, which was less than the incidence of 5.6% PDPH from Quincke 27G for the spinal block in the report from Corbey et al[12]. The lower incidence in the CSE group may be caused by a protective effect against further loss of cerebrospinal fluid from the injection of local anesthetic into the epidural space[13-16]. The dural hole made by the 27G spinal needle is extremely small, it was virtually impossible to force an 18G epidural catheter through this hole. Holmstrom et al[17] studied in fresh cadaver and found that after five dural punctures with the 25G spinal needle, the epidural catheter penetrated the perforated dura in 5% of cases.

CSE can be performed with many techniques. However, the single segment needle through needle technique is the most popular[3]. This technique is less traumatic, more acceptable to the patient and decreases the incidence of accidental dural puncture by epidural needle but requires a special CSE needle that is more expensive and not available in Thailand at this time. In the present study, the authors used the double needle technique at the same space after skin local infiltration

to blind the patients. Although Holst et al[18] could not identify metal particles abraded by the spinal needle from the inner ground edge of the Tuohy needle, it may unable to get the spinal fluid from the spinal needle, which was inserted inside the Tuohy since the spinal needle was not in the real midline and did not penetrated the dura. Moreover, the Quincke 27G, which is widely available in Thailand, is sometimes too short to penetrate the dura if inserted through the Tuohy needle with needle through needle technique.

In both groups, 3 ml of 0.25% bupivacaine was used as a test dose after a negative aspiration. Epinephrine was not added into the test dose since cycling changes in the maternal heart rate during labor complicates the interpretation of tachycardia due to intravascular injection of epinephrine. It is very important to frequently aspirate the epidural catheter and incrementally inject the drug together with observing the symptoms of the intravascular injection of the local anesthetic agent. An intravenously placed catheter is suspected when the patients develop dizziness, tinnitus, metallic taste on the tongue or the pain persists after the patient received an adequate amount of epidural analgesic drug[19]. If the epidural catheter was misplaced into the intrathecal space, 0.25% bupivacaine 3 ml caused analgesic levels up to T12 and above within 10 min[20]. For the CSE group, fentanyl 25 mcg caused the analgesic level up to T6 and it was difficult to differentiate it from the intrathecal injection of 0.25% bupivacaine 3 ml[11]. For this reason, besides testing the position of the epidural catheter with 3 ml of 0.25% bupivacaine, the authors also aspirated and slowly infused the medication through the epidural catheter together with the observation of the symptoms of the intravascular injection as well as observing the level of analgesia and motor blockage. However, these may have delayed the diagnosis of intrathecal displacement of the epidural catheter in the CSE group since it was difficult to identify this problem in this group.

No difference was seen in respect to motor blockage and mode of delivery in the present study. Intrathecal 'opioid only' as part of CSE did not show any significant advantage in terms of motor blockage in the present study since most of the patients in the CSE group required additional 0.25%bupivacaine bolus. The incidence of cesarean section in the present study was high compared to the study by Norris et al[6]. Since the most common indication for cesarean section in the present study was dystocia, appropriate selection and the performance of cesarean section instead of trying vaginal delivery may decrease the incidence of cesarean section. However, the number of patients in the present study was too small to identify the real incidence of each mode of delivery.

In the present study, the CSE group developed significantly more frequent pruritus than the epidural group, which is the same as the study by Palmer et al[7]. The symptom was mild and all the patients resolved without any treatment. Other side effects include maternal hypotension, shivering, nausea and vomiting were not different. Albright et al reported fetal bradycardia after intrathecal sufentanil 10 mcg as part of CSE for labor, caused five of 400 patients to require emergency cesarean section[21]. The authors were unable to identify fetal bradycardia after intrathecal fentanyl injection in the present study. These may be under detection since the authors did not continuously monitor the fetal heart rate. Even though the authors were unable to identify the relationship between epidural block and an APGAR score 6 at 5 minutes in four babies, continuous fetal heart rate monitoring may identify this group and may encourage prompt and proper management with better outcomes.

Conclusion

Combined spinal epidural analgesia for labor did not provide statistically significant faster onset of analgesia compared to the conventional epidural analgesia. A significant number of patients with intrathecal 'opioid only' as part of CSE required additional epidural bolus for adequate analgesia. CSE also increased the incidence of pruritus.

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การศึกษาเปรียบเทียบการใช้เทคนิคร่วม spinal-epidural เทียบกับ epidural สำหรับการระงับปวดระหว่างการเจ็บครรภ์คลอด

พรสวรรค์ งามประเสริฐวงศ์, กัญญา คำวิลัยศักดิ์, ตุลชัย อินทรัมพรรย์, แก้ว สุภรสุข, สุชีรา งามอุโฆษ

วัตถุประสงค์: เป็นการศึกษาผลทางคลินิกเปรียบเทียบการให้ fentanyl เข้าทางช่องไขสันหลัง ซึ่งเป็นส่วนหนึ่งของเทคนิคร่วม spinal-epidural analgesia (CSE) กับการให้ยาชาเข้าทางช่องเหนือดูรา(epidural) ด้วยวิธีมาตรฐาน

วัสดุและวิธีการ: ทำการศึกษาในหญิงตั้งครรภ์ครบกำหนดจำนวน 50 คนซึ่งได้รับการแบ่งเป็น 2 กลุ่มโดยการสุ่ม กลุ่มแรก (n = 25) ได้รับยา fentanyl 25 mcg เข้าทางช่องไขสันหลัง ตามด้วยการหยดยาต่อเนื่องตามสายที่วางไว้ในช่องเหนือดูรา ด้วย 0.0625% bupivacaine ผสมกับ fentanyl 2 mcg/ml ในอัตราเร็ว 12 ml/h กลุ่มที่สอง (n = 25) ได้รับ 0.25% bupivacaine 10 ml เข้าทางช่องเหนือดูรา หลังจากนั้นหยดยาต่อเนื่องตามสายในช่องเหนือดูรา แบบเดียวกับกลุ่มแรก บันทึกคะแนนความปวด, เวลาที่หายปวด, จำนวนครั้งที่ต้องการยาแก้ปวดเพิ่มเติม รวมทั้งผลข้างเคียงที่เกิดขึ้น

ผลการศึกษา: เวลาตั้งแต่เริ่มฉีดยาครั้งแรกจนผู้ป่วยหายปวดไม่แตกต่างกันอย่างมีนัยสำคัญทางสถิติ (7.8 $\pm$ 4.3 นาที ในกลุ่ม CSE เทียบกับ 10.2 $\pm$ 5.1 นาทีในกลุ่ม epidural, p = 0.085) ผู้ป่วยส่วนใหญ่ในกลุ่ม CSE ต้องการยาเพิ่มเติมทางช่องเหนือดูราเพื่อระงับปวด (80% ในกลุ่ม CSE เทียบกับ 48% ในกลุ่ม epidural, p = 0.038) ไม่พบความแตกต่างของการกดการทำงานของกล้ามเนื้อขณะคลอด หรือวิธีการคลอด พบอุบัติการณ์ของอาการคันในกลุ่ม CSE มากกว่ากลุ่ม epidural อย่างมีนัยสำคัญ (68% เทียบกับไม่มีรายใดเลยที่คันในกลุ่ม epidural, p = 0.00) อย่างไรก็ตามอาการทั้งหมดเป็นเพียงเล็กน้อย ผู้ป่วยทั้งหมดไม่ต้องการรักษา ไม่พบความแตกต่างของภาวะแทรกซ้อนอื่น ๆ

สรุป: การให้ fentanyl เข้าทางช่องไขสันหลังเพื่อเป็นส่วนหนึ่งของเทคนิค CSE ไม่ทำให้ออกฤทธิ์แก้ปวดได้เร็วขึ้นอย่างมีนัยสำคัญทางสถิติ เมื่อเทียบกับการใช้ยาชา bupivacaine เข้าทางช่องเหนือดูรา ผู้ป่วยส่วนใหญ่ในกลุ่ม CSE ต้องการยาชา bupivacaine เข้าทางช่องเหนือดูราเพิ่มเติมสำหรับฤทธิ์ระงับปวด และมีอุบัติการณ์ของการคันมากกว่า