Original Research Article

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A Comparative Study of Combined Spinal Epidural with Epidural for Labour Analgesia Using Lower Concentrations of Bupivacaine and Fentanyl

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Abstract

Aim: 1. To compare the analgesic efficacy of combined spinal epidural with epidural for labour analgesia using lower concentrations of Bupivacaine and Fentanyl. 2. To asses the effects of these agents on the maternal physiology, progress and duration of labour, mode of delivery, foetal and neonatal outcome. *Methods* : A total of 40 labouring parturients of ASA 1 & 2 have been divided in to 2 groups (Epidural group & Combined Spinal Epidural group) with 20 in each group. Epidural group received 10 ml of 0.0625% Bupivacaine and 50 mcg of Fentanyl epiduraly as initial bolus, followed by intermittent epidural top ups of 7 ml of 0.0625% Bupivacaine and 2mcg/ml of Fentanyl every 1 hr. Combined Spinal Epidural group received 1.5 ml solution containing 0.625 mg of Bupivacaine and 25 mcg of Fentanyl intrathecally and followed 2 hrs later by intermittent top ups of 6 ml of 0.0625% Bupivacaine and 2mcg/ml of Fentanyl every 1 hr. *Results* : With respect to the onset and quality of analgesia in Epidural and CSE groups, there were statistically significant differences. Analgesic efficacy was compared in terms of Time of first painless contraction, Time of loss of sensation to pin prick, visual analogue pain scales during first and second stage, Episiotomy pain relief and global assessment of quality of analgesia. CSE group showed statistically significant differences in terms of onset and quality of analgesia. No significant variations in duration and mode of delivery, maternal side effects and neonatal outcome. *Conclusion*: CSE when compared to plain Epidural produced statistically significant pain relief and the side effects produced by combining Fentanyl and Bupivacaine on maternal power, passage and passenger were minimal, proving that the CSE is a safer and good alternative to epidural for labour analgesia.

Keywords: Bupivacaine; Combined Spinal Epidural; Epidural; Fentanyl; Parturients; Foetus.

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Introduction

Pain is an unpleasant sensation localised to a part of the body. Is is often described in terms of a penetrating or tissue destructive process or of a bodily or emotional reaction . Labour pain has the important biologic function of indicating the gravida that labour is imminent. It should be effectively relieved once it has served its function, because persistent severe pain has harmful effects on the mother and on the foetus and the newborn.

There are several methods available for relieving labour pain, among them regional anaesthesia technique is the most popular.

Current obstetric analgesia practice aims to provide effective pain relief while minimising motor blockade. Lowering the concentration of Bupivacaine in epidural infusions has reduced the

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occurrence of motor blockade but even with dilute Bupivacaine infusions, moderate to sever motor blockade has been shown to occur in almost 44% of women. Motor blockade has been shown to reduce maternal satisfaction with epidural analgesia.

Efforts to improve epidural analgesia led to the anaesthesiologists popularising the Combined Spinal Epidural technique (CSE) for analgesia in labour. This technique involved an initial intrathecal injection of opioid (Fentanyl) and Bupivacaine to establish analgesia and subsequent epidural injections to restore and maintain analgesia. The doses of drugs involved were such that ambulation in labour was possible without any functional impairment of balance.

Methods

After obtaining proper written informed consent from the patients and approval of institutional ethical committee, 40 labouring parturients of ASA physical status 1 and 2 were included in the study. Inclusion criteria were nulliparous women in the age group of 18-24 years, uncomplicated pregnancy, active labour (cervical dilatation of 2-3 cm), single Foetus in vertex presentation, gestational age >37 weeks and ASA 1 and 2. Exclusion criteria were ASA 3 and 4, very early labour, complicated pregnancies, malpresentation/multiple pregnancy and gestational age <37weeks, bleeding diathesis local sepsis and women those who have received concomitant parenteral opioids.

This study was conducted in a prospective randomised manner and a total of 40 labouring parturients were included, equally divided in to 2 groups. Epidural group (E) and Combined Spinal Epidural (CSE) group. Epidural group received 10 ml of 0.0625% Bupivacaine and 50 mcg of Fentanyl epiduraly as initial bolus, followed by intermittent epidural top ups of 7 ml of 0.0625% of Bupivacaine and 2mcg/ml of Fentanyl at regular time intervals of 1 hour. CSE group received 1.5 ml solution containing 0.625 mg of Bupivacaine and 25 mcg of Fentanyl intrathecally and followed 2 hours later by intermittent epidural top ups of 6 ml of 0.0625% Bupivacaine and 2 mcg/ml of Fentanyl at regular time intervals of 1 hour.

In this study 0.5% Bupivacaine Hydrochloride manufactured by **Neon Pharma**, Fentanyl citrate 50 mcg/ml manufactured by **Neon Laboratories Ltd.** and Normal saline by **Parenteral Drugs (India) Ltd.** were used. All the solutions were prepared under strict aseptic conditions by the anaesthesiologists involved in the administration of the technique.

The Specific Gravity of the injected solution was 1.009 and was hyperbaric relative to Cerebro Spinal Fluid (1.006)

In this study, Combined spinal Epidural technique was performed with PORTEX CSE kit and epidural technique was performed with VYGON Tuohy epidural needle.

Before starting the procedureVisual Analogue Scale (VAS) was explained to the patients, where '0' represented no pain and '10' represented worst possible pain.

In the operating room appropriate equipments for airway management including Paediatric endotracheal tubes and all emergency drugs including opioid antagonists were kept ready. Patient was shifted to the operating theatre with the left lateral tilt when the labour was well established with cervical dilatation of 2-3 cm, the horizontal position of the operating table was checked and the patient was placed on it.The non invasive BP monitor, pulse oximetry were connected and baseline maternal pulse rate, BP, respiratory rate, SpO2 and foetal heart rate were recorded. All these patients were preloaded with 500 ml Ringer lactate after securing IV line with 18G venous cannula.

Under strict aseptic precautions group E patients received lumbar epidural in right lateral position using a Tuohy needle at L2-3 interspinous space and epidural space was identified by loss of resistance to air and 19G epidural catheter was then passed cephalad. After negative aspiration test, a test dose of 3 ml 1% Lidocaine with 15mcg of Epinephrine was given to rule out intravascular or intrathecal catheter placement. 5 minutes after the test dose these patients were given 10 ml of 0.0625% Bupivacaine with 50mcg of Fentanyl as initial bolus, followed by intermittent epidural top ups of 7ml of Bupivacaine 0.0625% and 2mcg/ml of Fentanyl at regular time intervals of one hour.

In CSE group patients using CSE kit lumbar epidural space was identified first then 27G pencil point spinal needle (needle through needle technique) was inserted through the epidural needle and after reaching the subarachanoid space 1.5 ml of solution containing 0.625mg of Bupivacaine with 25mcg Fentanyl was given over 10 seconds.Then 19 G epidural catheter was advanced in the epidural space. Top ups of 6ml of 0.0625% Bupivacaine with 2mcg/ml of Fentanyl were given 2 hours later then at regular time intervals of 1 hour. Epidural test dose was purposely omitted to avoid interference with spinal analgesia level.

During the late first and second stages of labour, both the groups were given 10ml of 0.0625% Bupivacaine and 2mcg/ml of Fentanyl in the sitting posture. All the patients in both groups have received oxytocin infusion 5 units in 500 ml of 5% dextrose to augment labour.

Maternal heart rate, BP, SpO2, respiratory rate and foetal heart rate were monitored at 2, 5, 10, 15, 30, 45 minutes after first bolus and then every 30 minutes. Labour progress was assessed by hourly pervaginal examinations by the obstetrician to assess the degree of cervical dilatation.

The time to first painless contraction was taken as the onset of analgesia which was also assessed by loss of sensation to pin pricks. Duration of analgesia was defined as the time interval between intrathecal injection and request for epidural top up.

Motor blockade was assessed using a modified Bromage scale at 5 minutes interval.

0 = Able to raise straight leg against resistance

1 = Unable to raise straight leg but able to flex knee

2 = unable to flex knee but able to flex ankles

3 = unable to move hip, knee or ankle

Analgesia assessment were carried out at 5 minutes interval throughout the study period. Testing for cold and pinprick was performed at 2 minutes interval for the first 20 minutes and every 5 minutes thereafter. Vibration sense was assessed with tuning fork tested at both the knee and the ankle. Proprioception was assessed by testing the joint position sense at the metatarsophalangeal joint of both big toes. Both these functions were tested with the patients eye closed, at 2 minutes interval for first 20 minutes and every 5 minutes thereafter.

The presence and occurrence of maternal complications like dural puncture, pruritus, urinary retention, sedation, nausea vomiting and respiratory depression were recorded .

The sedation was assessed by a bedside sedation scale..

0 = patient alert

1 = mild - occasionally drowsy; easily aroused

2 = moderate - frequently drowsy ; easily aroused

3 = somnolent ; difficult to arouse

Mode of delivery was noted and if instrumental or caesarean, the reasons were noted.

Episiotomy pain relief was assessed by a simple grading,

0 = no pain

1 = tolerable pain

2 = intolerable pain

Duration of all stages of labour were noted.

Neonatal outcome was assessed by APGAR score (Table 1) at 1, 5 and 10 minutes.

Table 1: APGAR score

SIGN	Score 0	1	2
Heart rate	Absent	< 100/min	> 100/min
Respiratory Effort	Absent	Slow, irregular	Good, crying
Colour	Blue, pale	Body pink, extremities blue (Acrocyanosis)	Completely Pink
Reflex irritability	Absent	Grimace	Cough, sneeze
Muscle tone	Limp	Some flexion of extremeities	Active motion

Statistical analysis

Mean and Standard deviation were estimated from samples of each study group. Mean values were compared by students independent 't' test. Proportion of different characteristics and categorical variables were estimated from each study group which were compared by Chi-square test (M x N), Chi-square with Yates continuity correction, Fischers exact test appropriately. In this study 'p' value < 0.05 was considered as level significance.

Results

Patients in both the groups were similar with respect to age, height, weight, gestational age, cervical dilatation, visual analogue pain scale before procedure (Table 2).

Onset of analgesia was analysed by both objective and subjective measures (Figure 1 & Table 3).

The mean time of onset of loss of first painless contraction and loss of sensation to pin prick were faster in CSE group which were statistically significant.

Visual Analogue Pain scale (Mean±SD) (Table 4).

Table 2: Maternal Characteristics Mean +/- SD

	E Group	CSE Group	P value	Significance
Age in years	20.4 +/- 1.2	20.35 +/- 1.9	0.76	NS
Height (cm)	150.1 +/- 3.8	151.75+/- 1.03	0.76	NS
Weight (kg)	53.8+/- 3.2	53.3+/- 3.5	0.64	NS
Gestational age (Wks)	39+/- 1.3	38.5+/- 1.4	0.25	NS
Cervical dilatation (cm)	3.4 +/- 0.5	3.5 +/- 0.62	0.58	NS
VAS base	7.9 +/- 0.5	8.2 +/- 0.5	0.07	NS

Table 3: Onset of Analgesia (Mean +/- SD)

	E Group	CSE Group	P value	Significance
Time of first painless contraction (sec)	523.1 +/- 121.9	259.5 +/- 20.2	<0.0001	S
Onset of loss of sensation to pinprick (sec)	480.0 +/- 77.9	183.0 +/- 16.1	<0.0001	S

Table 4: Visual Analogue Pain Scale (Mean +/- SD)

	E Group	CSE Group	P value	Significance
First stage	1.46 +/- 0.37	1.01 +/- 0.06	<0.0001	S
Second stage	3.55 +/- 0.51	3.15 +/- 0.37	<0.007	S

Table 5: Episiotomy Pain Relief

	E Group (n = 19)	CSE Group (n=18)
0	3(15.7%0	0
1	14 (73.6%)	16 (88.8%)
2	2 (10.5%)	2(11.1%)
0 = No Pain	1 = Tolerable pain	2 = Intolerable pain

Table 6: Global Assessment of Quality of Analgesia

	E Group(n =20)	CSE Group (n=20)
0	0	0
1	17(85%)	17(85%)
2	3(15%)	3(15%)
0= Worse than expected	1 = about as expected	2 = better than expected

Table 7: Maximal Height of Sensory Blockade

	E Group(n =20)	CSE Group (n=20)
>T6	0	0
T6 - T10	19	18
<T10	0	0

Table 8: (Maximal Motor Blockade)

Modified Bromage scale	E Group(n =20)	CSE Group (n=19)
0	17(85%)	18(84.7%)
1	3(15%)	1(5.2%)
2	0	0
3	0	0

Table 9: Maternal Vital Signs

	E Group	CSE Group	P value	Significance
Pulse rate	96.8 +/- 6.6	88.4+/- 4.6	<0.0001	S
Respiratory rate	18.7 +/- 1.6	17.0 +/- 1.4	0.25	NS
SpO2	98.6 +/- 0.8	99.0 +/- 0.6	0.07	NS
SBP	120.8 +/- 5.8	108.0 +/- 2.8	0.04	S
DBP	79.0 +/- 3.8	74.1 +/- 5.3	0.002	S
MAP	92 +/- 4.2	85 +/- 3.2	0.04	S

VAS during first and second stages of labour showed statistically significant differences with better quality of analgesia in CSE group.

Duration of spinal analgesia was 120±16 minutes in the CSE group

Episiotomy pain relief (Table 5)

With regards to pain relief during episiotomy in epidural group, out of 19 mothers 14 had tolerable pain 2 had intolerable pain and 3 had no pain. In CSE group out of 18 mothers, 16 had tolerable pain and 2 had intolerable pain.

Global assessment of quality of analgesia (Table 6)

Mothers in postpartum period gave their opinion regarding the quality of analgesia which were comparable in both the groups.

Maximal height of sensory blockade (Table 7)

In both the groups, the maximal sensory level was confined to T6 - T10.

Maximal motor blockade (Table 8)

With regards to motor blockade as assessed by Modified Bromage Scale,in the Epidural group 17 had no motor blockade and 3 had grade 1 motor blockade and in CSE group 8 had no motor blockade and 1 had grade 2 motor blockade.

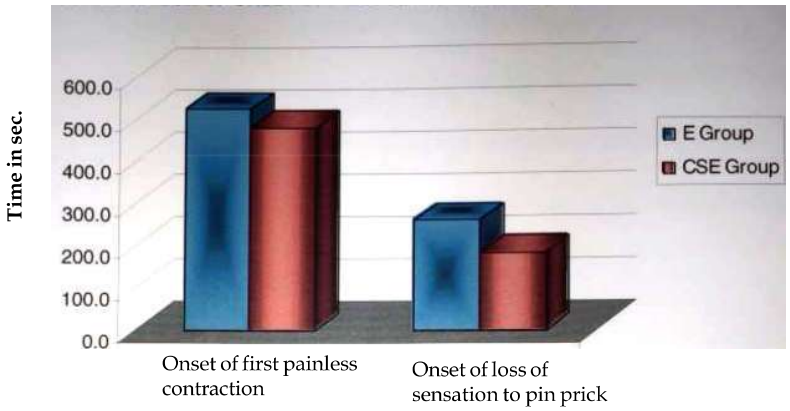
Maternal vital signs (Fig. 2, Fig. 3 & Table.9)

The maternal vital signs like pulse rate, SBP and DBP were showing statistically significant differences in CSE group.No significant differences were observed in respiratory rate and SpO_2.

Mode of delivery (Table 10)

There were not much differences in mode of delivery in both the groups. One mother in CSE group have been taken up for

Comparison of onset by subjective and objective measures



Comparison of mean visual analogue scale

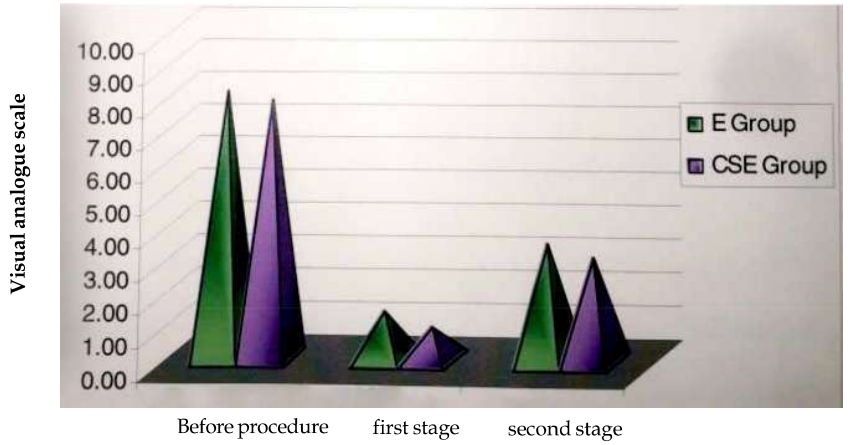


Fig. 1:

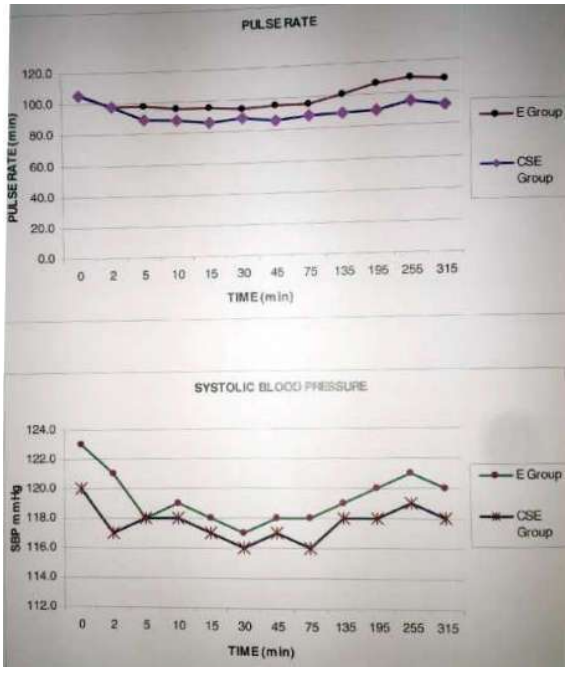


Fig. 2:

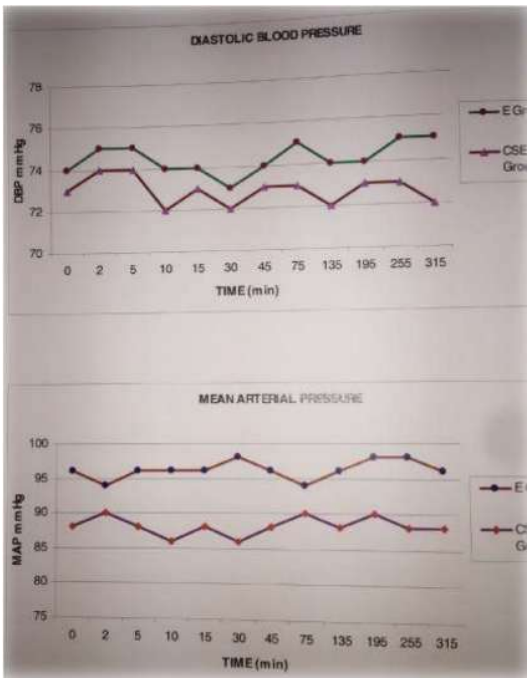


Fig. 3:

Table 10: Mode of Delivery

	E Group (n =20)	CSE Group (n =20)
Natural	19 (95%)	18 (90%)
Outlet forceps	1 (5%)	1(5%)
Low mid cavity forceps	0	0
Caesarean	0	1(5%)

Table 11: Duration of Labour

Duration of Labour (min)	E Group (n = 20)	CSE Group (n = 20)	P Value	Significance
Total duration	266 +/- 56.5	273.8 +/- 34.6	0.60	NS
First Stage	221.0 +/- 44.9	218.5 +/- 35.6	0.85	NS
Second stage	55.0 +/- 15.2	59.3 +/- 11.8	0.06	NS

Table 12: Maternal Side Effects

	E Group(n =20)	CSE Group (n =20)
Dural puncture	0	0
Venous punture	1	0
Pruritus	0	12
Urinary retension	14	12
Nausea/Vomiting	1	0
Rigor	0	0
Sedation	0	0
Hypotension	0	0
Respiratory depression	0	0

Table 13: Foetal Heart Rate

	E Group	CSE Group	P value	Significance
FHR	128 +/- 2.9	129+/- 2.0	0.90	NS

Table 14: Newborn APGAR Score

		E Group (n=19)	CSE Group(n=19)
1 min	<7	1	1
	7-10	19	19
5 min	<7	0	0
	7-10	20	20
10 min	<7	0	0
	7-10	20	20

caesarean section due to obstetric reason.

Duration of labour(Table.11)

The mean duration of first and second stages of labour as well as total duration of labour did not show any significant differences.

Maternal side effects (Table. 12)

The incidence of side effects varies. Almost 60% of parturients of CSE group had pruritus which was peculiar to this group which was relieved without any measures. 70% of epidural groups and 60% of CSE group had urinary retention. No mothers in both the groups had sedation, rigor, hypotension or respiratory depression.

Foetal heart rate (Table 13)

No significant differences were observed in both the groups.

Newborn APGAR score (Table 14)

Except one new born in both the groups who had APGAR score of 6 at 1min, all others had APGAR score of above 7 at 1 min. These 2 newborns were admitted in newborn intensive care unit for observation and got discharged after 2 days with out any problems.

Discussion

Labour pain is the only physiological function in the body which gives rise to pain during child birth. The parturient often must work hard through distressing, exhausting long hours to deliver her baby. Is it necessary to allow the parturient to experience pain in this scientific era? The main focus of this study was providing adequate pain relief with minimal side effects on maternal power (uterine activity and progress of labour), passage(birth canal), passenger (Foetus).

In this study we have compared CSE with Epidural to provide adequate analgesia during labour.

(1) Lee et al. 1999, compared the effects of 2 doses of intrathecal fentanyl and Bupivacaine

(2) Palmer et al. 1999, proved that addition of Fentanyl to Bupivacaine for intra thecal labour analgesia modestly increases the duration and speeds the onset of analgesia.

The mean time of onset of first painless contraction was 523.1±121.9 sec on "E" group and 2 59.5±20.2 in CSE group, a 50% reduction in latency.

The mean time for onset of loss of sensation to pinprick was 480.0±77.9 sec in "E" group and 183.0 ±16.1 in CSE group, a 60% reduction in onset time.

The quality of analgesia in terms of percentage reduction were 80% in first stage and 55% in seconds stage in "E" group compared to 85% in first stage and 60% in second stage in CSE group.

With respect to episiotomy pain relief 80% of cases in both "E" and CSE groups had tolerable pain and 20% cases of both groups had intolerable pain.

Pain relief as assessed by the patient indicate 85% had about as expected, 15% better than expected, 0% had worse than expected level pain relief in both groups.

Maximal upper level of sensory blockade was confirmed to T6-T10 in 100% of patients in both the groups.

Maximal motor blockade assessed by modified Bromage scale showed 94% of cases in CSE group with grade 0 motor blockade compared with 84% cases of "E"group. Only 6% of cases in CSE group had grade 1 motor blockade compared with 16% cases in "E" group.

Haemodynamic stability was better in CSE group when compared with E group

The incidence of forceps delivery was 5% in both the groups

Incidence of caesarean section was 5% in CSE group compared with 0% in E group

The commonest side effect observed was urinary retention in 70% of cases in E group Vs 60% in CSE group

Almost 60% of cases in CSE group had pruritus compared with 0% in E group.

No significant variation in foetal heart rate recorded in both the groups

No significant variation in neonatal outcome in both the groups.

Conclusion

From this study it is concluded that combined spinal epidural technique produced statistically significant pain relief when compared to epidural alone. The side effects produced by combining Fentanyl and Bupivacaine on maternal power, passage and passenger were minimal, proving that the CSE is a safe and good alternative to epidural for labour analgesia.

References

1. Almufti R, Morey R , Shennan A, Morgan. Blood pressure and heart rate changes with patient controlled combined spinal epidural analgesia while ambulating in labour; Br.J. Obstret Gynaecol 1997 May;104(5); 554-8.
2. Ashokumar B, Newman LM, McCarthy RJ, Ivan Kovich AD, Tuman KJ. Intrathecal Bupivacaine reduces pruritus and prolong duration of Fentanyl analgesia during labour; Anaesth. Analg. 1998 Dec; 87(6);1309-15.
3. Bromage PR - Epidural Analgesia 1978; Philadelphia, Wb Saunders.
4. Calimaran AL Strauss - Holder TP, Wang WY, McCarthy RJ, Wong CA. The effect of Epidural test dose on motor function after a combined spinal epidural technique for labour analgesia; Anaes. Analg. 2003 Apr;96(4):1167-72.
5. Cutbush CM, NcDonough JP, Clark K, McCarthy EJ - The effect of Intrathecal and epidural narcotic analgesia on the length of labour ; CRNA 1998 Aug; 9(3):106-12.
6. Danilo Celleno, Giorgio Capogna - Epidural Fentany plus Bupivacaine 0.125% for labour analgesia - Can J. Anaesth. 1998;35(4);375-378.
7. Deballi P,Breen TW; Intrathecal opioids for combined spinal epidural analgesia during labour - CNS drugs 2003;17(12):889-904.
8. Dresner M, Bamber J, Calow C, Freeman J, Charlton P - Comparison of Low dose epidural with combined spinal epidural analgesia for labour; Br. J Anaesth. 1999 Nov;83(5):756-60.
9. Fernando R, Bonello E, Gill P, Urquhashi J, Reynolds F, Morgan B - Neonatal welfare and placental transfer of Fentanyl and Bupivacaine during ambulatory combined spinal epidural analgesia for labour; Anaesthesia 1997 Jun;52(6);517-24.
10. Hepner DL,Gaiser RR, Cheek Tg, Gutsche BB - Comparison of combined spinal epicurean and low dose epidural for labour analgesia. Can J Anaesth. 2000 March;47(3):232-6.
11. Hughes D, Hill D, Fee Jp- Intrathecal Ropivacaine or Bupivacaine with Fentanyl for labour; Br J Anaesth. 2001 Nov;87(5);733-7.
12. Norris MC, Grecio Wm, Barkowski M, Leighton BL, Arkoogh KA, Huffnagle HT, Huffnagle S- Complications of labour analgesia - epidural vs combined spinal epidural techniques. Anaesth.Analg. 1994 Sep;79(3) 529-37.
13. Palmer Cm, Van Masin G, Nogam WM, Alver D- Bupivacaine augments intrathecal Fentanyl for labour analgesia - Anaesthesiology 1999 Jul;91(1):84-9.
14. Sia AT, Camann WR, Ocampo CE,Goy RW, Tan HM - Is the combined spinal epidural a good alternative to

conventional epidural? Singapore Med. J 2003 Sep; 44(9):464.

15. Tech WH, Sia AT - Hyperbaric Bupivacaine 2.5 mg prolongs analgesia compared with plain Bupivacaine when added to intrathecal Fentanyl 25mcg in advanced labour; Anaesth.Analg.2003 Sep;97(3): 873-7.
16. Walton P, Reynolds F - Epidural analgesia and instrumental delivery; Anaesthesia 1984;34(2)218-23.
17. Hawkins JL. Epidural analgesia for Labour and delivery. N Engl J Med. 2010;362:1503–10 [PubMed].
18. Birnbach DJ. Advances in labour analgesia. Can J Anesth. 2004;51:R1–3.
19. Simmons SW, Cyna AM, Dennis AT, Hughes D. Combined spinal-epidural versus epidural analgesia in labour. Cochrane Database Syst Rev. 2007;3 CD003401 [PubMed].
20. Lyons GR, Kocarev MG, Wilson RC, Columb MO. A comparison of minimum local anesthetic volumes and doses of epidural bupivacaine (0.125% w/v and 0.25% w/v) for analgesia in labor. Anesth Analg. 2007;104: 412–5. [PubMed].
21. Chestnut DH, Laszewski LJ, Pollack KL, Bates JN, Manago NK, Choi WW. Continuous epidural infusion of 0.0625% Bupivacaine-0.0002% Fentanyl during second stage of labour. Anesthesiology. 1990;72:613–8. [PubMed].
22. Leighton BL, Halpern SH. The effect of epidural analgesia on labor, maternal and neonatal outcomes: A systematic review. Am J Obstec Gynecol. 2002;186: S69–77. [PubMed].