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Combined spinal epidural for labor analgesia comparison of two different doses of intrathecal bupivacaine 1.25 mg and fentanyl 25 μg with bupivacaine 2.5 mg and fentanyl 25 μg

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ABSTRACT

Background and Objective: The responsibility of the anesthetist in obstetrics is very high. This study compares two different low doses of intrathecal bupivacaine 1.25 mg and 2.5 mg along with 25 μg fentanyl as the spinal component of combined spinal epidural (CSE) analgesia in the early part of labor, followed by epidural top-up.

Methodology: Approval was obtained from the institutional review board and written informed consent was obtained from 60 healthy term primigravida or the second gravid parturients, with cephalic singleton pregnancy between 36 and 42 weeks, ASA Grade I/II patients. The study was conducted using low-dose intrathecal bupivacaine 1.25 mg and fentanyl 25 μg (Group I) with bupivacaine 2.5 mg and fentanyl 25 μg (Group II) as the spinal component of CSE analgesia in the early part of labor. We compared the two with respect to their onset, duration of sensory and motor block, quality of analgesia during early part of labor and the side effects of the drugs.

Results: The onset of analgesia was equally rapid with both groups within 5 min, lower incidence of motor block with Group I compared to Group II. Duration of analgesia was longer in Group II, associated with higher dermatome levels of sensory block with longer time for regression of the block.

Coclusion: We found that bupivacaine 1.25 mg was as effective as bupivacaine 2.5 mg when added to fentanyl 25 μg for CSE.

Key words: Bupivacaine, fentanyl, Labour analgesia

INTRODUCTION

Unrelieved stress in labor produces increased plasma cortisol and catecholamines concentrations which reduce uteroplacental blood flow[1] by 35–70% compounding the effects of hyperventilation on the oxygen supply to the fetus.

Metabolic acidosis as a result of increased metabolic rate, especially in the second stage of labor is transferred to the fetus. There is delayed gastric emptying and urinary emptying.[2]

Effective pain relief reduces plasma noradrenaline,[3] prevents the rise during the first and second stage of labor of 11-hydroxycorticosteroid,[4] and prevents metabolic acidosis by reducing the rate of rise of lactate and pyruvate.[5] It decreases maternal oxygen consumption by up to 14%.[4]

The pain-induced hyperventilation and hypocapnia[6] reduces uteroplacental blood flow by up to 25%. The respiratory alkalosis further impairs fetomaternal gas exchange by shifting the oxyhemoglobin dissociation curve to the left and fetal PaO_2 may fall up to 23%.[6]

Various techniques available for pain relief during labor includenon-pharmacological methods, pharmacological methods, inhalational analgesics, systemic analgesics, and regional techniques.

Low-dose combined spinal epidural (CSE) analgesia has gained widespread acceptance as an approach to labor analgesia. The rapid onset of analgesia is one of the major advantages of CSE analgesia and with its increased association with maternal satisfaction.[7]

CSE analgesia is an effective method of analgesia in labor. Intrathecal administration of combination of local anesthetic and lipophilic opioid provides rapid analgesia.

The present study compares the efficacy of low dose of bupivacaine 1.25 mg and 2.5 mg with fentanyl 25 μg intrathecally (single dose) in terms of onset, duration of block, and quality of analgesia during labor, followed by epidural analgesia.

Objectives of the study

1. To study the onset and duration of sensory and motor block in early part of labor with two different low doses of intrathecal bupivacaine (1.25 mg and 2.5 mg) along with 25 μg fentanyl.

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2. To study the quality of analgesia during early part of labor.
3. To study the side effects of the drugs.

METHODOLOGY

Patients Selection

a. Healthy primigravida and gravida 2 patients at term.
b. ASA I and ASA II.
c. Maternal request for epidural analgesia.
d. Age group of 18–35 years.
e. Women in active labor with cervical dilatation in primi about 4–5 cm and gravida 2 with cervical dilatation of 3–4 cm.

Exclusion Criteria

The following criteria were excluded from the study:

a. Patients unwilling for procedure.
b. Parturient with gravid 3 or more.

Inclusion Criteria

The following criteria were included in the study:

- Parturients with multiple pregnancies.
- Pregnancy-induced hypertension.
- Severe anemia.
- Cephalopelvic disproportion.
- Previous lower segment cesarean section.
- History of antepartum hemorrhage.
- History of allergy to local anesthetic.
- History of cyclic vomiting syndrome/RS disease.
- History of bleeding disorders.
- Diabetes mellitus.
- History of psychiatric/neurologic disease.

Methodology

About 60 parturients with ASA I and ASA II in established labor with cervical dilatation <5 cm were randomly selected informed written consent was taken from patients.

Group I received intrathecal injection bupivacaine 1.25 mg and injection fentanyl 25 μg.

Group II received intrathecal injection bupivacaine 2.5 mg and injection fentanyl 25 μg for CSE.

Procedure

After infiltration of local anesthetic using needle through needle technique 18 Gauge Tuohy needle, epidural space was identified with loss of resistance to air technique. Then, a 15 mm (25 G) long "Whitacre" spinal needle was introduced through the epidural needle, and the correct position of the tip in the intrathecal space was confirmed by observation of free flow of cerebrospinal fluid.

Patients were allocated randomly to receive intrathecal injection of bupivacaine 1.25 mg (0.5% bupivacaine 0.25 ml) with fentanyl 25 μg (Group I n = 30) or bupivacaine 2.5 mg/0.5% bupivacaine 0.5 ml) with fentanyl 25 μg (Group II, n = 30) both made up to total volume of 2 ml with saline.

Patients visual analog scale (VAS) pain score was recorded every 5, 10, 15, 30, 45, 60, 75, 90, 105, and 120 min, i.e., (every 5 min for 15 min and then every 15 min for 2 h) until the next request for analgesia.

After positioning the patient in supine position, onset of analgesia and dermatomal level were checked by loss of sensation to pinprick, time of onset, and degree of motor blockade was checked by Bromage classification.

VAS pain score for all patients at the next request for analgesia was recorded and the study was terminated. Continuation of epidural analgesia was done with 0.125% bupivacaine + 2 μg fentanyl in 10 ml.

Monitoring - mother's vital parameters, progress of labor, efficacy of analgesia, and fetal welfare were watched in coordination with attending obstetrician and all standard monitoring required.

Parameters Studied

The following parameters are studied:

1. Assessment of sensory blockade - sensory blockade assessed by pinprick and time noted for block to reach different dermatomal level.
   - Onset of sensory block
   - Maximum height reached and time required,
   - Duration of analgesia,
   - Quality of analgesia.
2. Assessment of motor block:
   - Motor blockade was assessed by Bromage scale.
   - Time required for complete recovery.
3. Untoward effects:

The patients were carefully monitored for any untoward effects such as inadequate block, hypotension, bradycardia, respiratory distress, nausea, vomiting, restlessness, pruritis, shivering, anaphylactic reaction, and fetal bradycardia.

Terms and Definitions

Time of onset of analgesia, this was taken as time from deposition of drug to the feeling of tingling sensation in the legs.

Time of onset of paralysis (motor blockade), this was taken as time from onset of paresis to loss of power, i.e., patient was not able to lift the legs (modified Bromage Scale, onset of motor block).

Duration to Reach Maximum Dermatomal Level

This was taken as the time interval between the deposition of drug and loss of sensation at highest dermatomal level.

Statistical Analysis

In the present study, results are given as mean ± standard deviation and range values for continuous data. Student's *t*-test was used to compare the two groups, categorical data are expressed as number and percentages, and the difference between the groups was compared by Chi-square test. *P* value of 0.05 or less was set for statistical significance.

RESULTS

Regarding age, height, and weight, *P* value is not significant [Tables 1-10 and Figure 1].

DISCUSSION

Obstetricians and anesthetists have always feared the incidence of instrumental deliveries in women receiving labor analgesia could be higher than in those who do not receive it.[8]

Table 1: Time of onset of sensory analgesia after spinal component of CSE

Parameter	Mean±SD		Mean difference	*P** value	Sig.
	Group I	Group II			
Sensory onset of action in seconds	204.33±53.06	87±30.61	117	<0.001	HS

P<0.001 was highly statistically significant. SD: Standard deviation, CSE: Combined spinal epidural

Table 2: Maximal dermatomal level of sensory blockade after spinal component of CSE

Dermatomal of level	Group I (%)	Group II (%)
T6	0	2 (7)
T7	0	11 (37)
T8	5 (17)	11 (37)
T9	13 (43)	4 (14)
T10	10 (33)	2 (7)
T11	2 (7)	0

χ^2=27.3 *P*<0.001 was highly statistically significant. CSE: Combined spinal epidural

Table 3: Grade of motor blockade after spinal component of CSE

Motor onset of action	Group I (%)	Group II (%)
0	26 (87)	18 (60)
I	4 (13)	9 (30)
II	0	3 (10)

χ^2=6.3 *P*=0.04 was statistically significant

Table 4: Changes in heart rate

Heart rate	Mean±SD		Mean difference	*P** value	Sig.
	Group I	Group II			
0	97±11	95±8	2.0	0.43	NS
1	80±8	81±15	−0.8	0.80	NS
5	80±9	82±6	−2.2	0.29	NS
15	79±6	80±7	−0.3	0.87	NS
30	79±7	80±8	−0.4	0.83	NS
45	79±7	77±8	1.8	0.37	NS
60	78±7	75±9	2.3	0.26	NS
90	82±5	75±7	6.6	<0.001	HS
180	81±6	75±6	5.5	0.001	HS

*Student's unpaired *t*-test. *P*<0.001 which was statistically significant. NS: Not significant, HS: Highly significant

Table 5: Changes in systolic BP

Systolic BP	Mean±SD		Mean difference	*P** value	Sig.
	Group I	Group II			
0	120±7	121±8	−0.4	0.84	NS
1	111±10	112±9	−1.5	0.52	NS
5	110±10	112±10	−1.8	0.48	NS
15	107±22	106±13	0.5	0.92	NS
30	113±9	106±13	7.0	0.02	S
45	117±13	110±13	6.3	0.07	NS
60	115±9	115±8	0.4	0.86	NS
90	117±8	115±7	2.1	0.29	NS
180	119±5	110±13	8.3	0.002	S

*Student's unpaired *t*-test. S: Significant, NS: Not significant, BP: Blood pressure

Table 6: Changes in diastolic blood pressure

Diastolic BP	Mean±SD		Mean difference	*P** value	Sig.
	Group I	Group II			
0	78±7	81±5	−2.6	0.10	NS
1	75±10	78±8	−2.9	0.21	NS
5	74±10	74±9	−0.1	0.98	NS
15	75±11	72±11	2.6	0.36	NS
30	77±±9	74±11	3.0	0.25	NS
45	75±10	75±10	−0.6	0.81	NS
60	78±10	77±8	1.4	0.56	NS
90	74±10	74±10	0.0	-	-
180	76±9	76±9	0.0	-	-

*Student's unpaired *t*-test. SD: Standard deviation

Table 7: Duration of two segment regression

Parameter	Mean±SD		Mean difference	*P** value	Sig.
	Group I	Group II			
Time of two segment regression in min	82.67±16.17	104.33±19.37	−21.6	<0.001	HS

P<0.001 which was highly statistically significant. SD: Standard deviation

Table 8: Epidural top-up needed or not after spinal

Epidural needed	Group I (%)	Group II (%)
Yes	29 (97)	23 (77)
No	1 (3)	7 (23)

χ^2=5.8. *P*=0.01

Table 9: VAS score

VAS after spinal	Group I (%)	Group II (%)
1–2	20 (67)	28 (93)
3–4	10 (33)	2 (7)

χ^2=6.7. *P*=0.01. Significant. VAS: Visual analog scale

Table 10: Complications

Parameter	Present cases		*P** value	Sig.
	Group I (%)	Group II (%)		
Sedation	10 (33)	11 (37)	0.78	NS
Fetal bradycardia	3 (10)	7 (23)	0.16	NS
Nausea	8 (27)	8 (27)	-	-
Vomiting	5 (17)	5 (17)	-	-
Pruritis	10 (33)	11 (37)	0.78	NS
Hypotension	3 (10)	13 (43)	0.004	S

*Chi-square test

Ideally, pain relief with regional techniques should be produced with the minimum disturbance to the progress of labor or to sympathetic functions, sensory functions (proprioception), and motor functions of central nervous system. Thus, it is intriguing

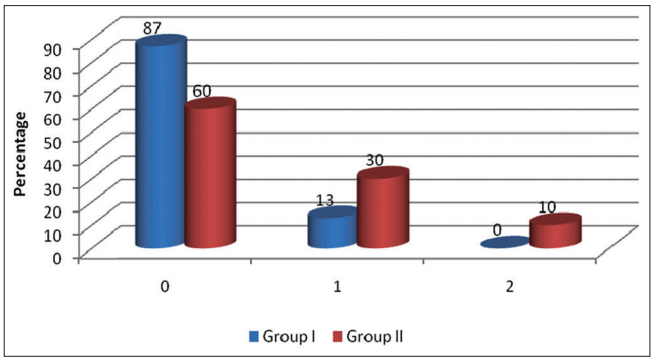

Figure 1: Grade of motor blockade after spinal component of combined spinal epidural

to the obstetric anesthetist to strike a balance between patient satisfactions by providing good analgesia, reduces motor block, thus making the parturient participate in labor, and decreases instrumental deliveries due to prolonged second stage.[9]

Factors contributing to instrumental delivery include:

a. Diminished pain and sensation from uterine contraction, leading to diminished Fergusson's reflex and of the perception of the need to push at full dilatation.
b. Reduced motor force due to weakened abdominal musculature and
c. Inadequate rotation of the presenting part due to weakened pelvic floor musculature.[10]

Lee *et al*. performed CSE at L2-3 or L3-4 intervertebral space using a single space needle through needle technique with 18G Tuohy needle and 25G Whitacre spinal needle.[7]

Collins *et al*. did comparison of CSE analgesia bupivacaine (2.5 mg) and fentanyl (25 μg) followed by epidural top-ups of 15 ml, 0.1% bupivacaine with 2 μg/ml fentanyl into epidural space. With standard epidural analgesia, 25 mg/10 ml of 0.25 % bupivacaine injected into epidural space followed by top-up of 6–10 ml 0.25% bupivacaine. Overall, satisfaction was greater in CSE group.58 Comparison of maternal satisfaction with low dose CSE (group A) and higher dose standard bupivacaine (group B) epidural analgesia. They concluded onset of analgesia was more rapid in combined spinal epidural group 20 min VAS score 92/98 group A Vs 68/99 group B $P<0.0001$. In our study the onset of analgesia was equally rapid with both doses of bupivacaine. Sensory onset of analgesia with mean of 204 sec in group I and 87 sec in group II and mean difference of 117 sec between both the groups.[11]

Dermatomal level achieved at the end of 10 min was T9 in group I and T7-T8 in group II with *P*-value of <0.001, motor blockade grade 0 in 87% of cases and grade 1 in 13% of cases in Group I. In group II Grade 0 60% of patients and 30% of patients with grade I blockade.

Duration of analgesia for spinal component, mean of 82 min in group I and 104 min in group II with mean difference of 21 min, *P*-value of 0.001.

Lee *et al*., VAS pain scores in the first 30 min were similar between the two groups. Median time to the first request for additional analgesia was longer in Group B (120 min) compared to Group A (75 min) *P* (0.0013).[7]

Michael J. Paech *et al.* did a randomized, double blinded controlled clinical trial aimed to determine whether the addition of subarachnoid clonidine 15-45 μg to fentanyl 20 μg and bupivacaine 2.5 mg increased the duration of labour analgesia they concluded that onset of analgesia and duration was almost similar addition of clonidine had increased incidence of hypotension. In the group with fentanyl and bupivacaine thoracic sensory dermatomal level was T5. Onset was within 5 min and duration was more than 90 min with small incidence of motor blockade.[12]

A study by Wong *et al*. revealed that neuraxial analgesia in early labor did not increase the rate of cesarean delivery, and it provided better analgesia and resulted in shorter duration of labor than systemic analgesia.[13]

The comparative obstetric mobile epidural trial study confirmed that low-dose techniques influence the mode of delivery in both CSE and low-dose infusion groups there was an increased percentage of spontaneous vaginal deliveries compared to traditional technique.[14]

In our study, spontaneous vaginal delivery occurred in 84% of cases in Group I and 63% of cases in Group II. Instrumental delivery with forceps was conducted in 13% of cases in Group I and 20% of cases in Group II. Cesarean section was done in 3% of cases in Group I and 17% of cases in Group II.[15]

They concluded that the concentration of bupivacaine and fentanyl achieved during the use of routine CSE for labor was not detrimental to the fetus.[15]

In our study, there was not much difference in fetal heart rate changes.

CONCLUSION

The onset of analgesia was equally rapid with both doses of bupivacaine, and the two groups achieved of excellent in major proportion within 5 min. Duration of analgesia was longer in patients who received the larger dose of bupivacaine. This was associated with higher dermatome levels of sensory block which was reflected in corresponding longer time for regression of the block.

We found lower incidence of motor block with bupivacaine 1.25 mg compared with bupivacaine 2.5 mg. Our results also showed a significantly smaller decrease in arterial pressure with bupivacaine 1.25 mg. This is important clinically as maternal hypotension affects uteroplacental perfusion.

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