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COMPARITIVE STUDY ON QUALITY OF ANALGESIA WITH TWO DIFFERENT DOSES OF EPIDURALLY ADMINISTERED BUPIVACAINE IN COMBINED SPINAL EPIDURAL LABOUR ANALGESIA

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ABSTRACT Combined spinal epidural analgesia is most preferred labour analgesia because of its good quality of analgesia.Eventhough labour analgesia which has many proven benefits, not popular in developing countries like india because of myths like increased rate of instrumental and operative delivery , increased risk of motor blockade which adversely affect the progress of labour. By using low dose and ultra low dose concentrations of local anesthetic agent decreases the adverse effects without affecting the quality of analgesia.In our study, we compare the combined spinal epidural technique with two different low concentrations of bupivacaine (0.0625% vs 0.1%) for quality of analgesia. To initiate analgesia we used intrathecal fentanyl 25 mcg in both the groups and we also add fentanyl 2mcg per ml in epidural preparations of bupivacaine to improve the quality in both the groups. Group I: receive intrathecal fentanyl 25µg+epidural 0.1% bupivaccaine 10 ml with 2µg of fentanyl/ml Group II: receive intrathecal fentanyl 25 µg +epidural 0.0625% bupivaccaine 10 ml with 2µg of fentanyl/ml Both the groups are comparable in age ,height ,weight, parity and timing of initiation of labour analgesia.Quality of analgesia was excellent in both groups which was assessed by patient's satisfaction at the end of delivery Onset of analgesia in both groups was comparable But the total dosage of bupivacaine used in group I was 29.67 mg with SD of 3.198, in group II mean was 18.02 with SD of 1.575. p-value of 0.0000 which was statistically very significant. 76.67% in group I and 80% in group II had experienced pruritus which was mild and self limiting in most of the parturients.

KEYWORDS : Analgesia,Bupivacine,Fentanyl,Epidural Anaesthesia

1. INTRODUCTION:

Neuraxial analgesia is the most commonly performed and safest technique among the available methods of labour analgesia. Among this , now a days combined spinal epidural analgesia is most preferred method because of its good quality of analgesia. Even though labour analgesia which has many proven benefits, not popular in developing countries like india because of myths like increased rate of instrumen tal and operative delivery , increased risk of motor blockade which adversely affect the progress of labour. By using low dose and ultra-low dose concentrations of local anesthetic agent decreases the adverse effects without affecting the quality of analgesia.

2.AIM & OBJECTIVES:

The aim of the study is to compare the quality of analgesia with two different doses of epidurally administered bupivacaine in combined spinal epidural labour analgesia after intrathecal administration of fentanyl 25 mcg. In group I 0.1% bupivacaine with fentanyl 2mcg and in group II 0.0625% bupivacaine with fentanyl 2mcg concentration is used.

3.METHODOLOGY :

This comparative clinical study of combined spinal epidural labour analgesia for vaginal delivery with intrathecal fentanyl 25 µg + epidural 0.0625% bupivaccaine 10 ml with 2µg of fentanyl/ml versus intra thecal fentanyl 25µg+epidural 0.1% bupivaccaine 10 ml with 2µg of fentanyl/ml will be conducted in 60 parturients , who wish and opt for painless labor after obtaining permission the Tamilnadu Dr MGR Medical university Ethical committee. After taking the written informed consent, Only those who fulfill the following criteria will be included in this study.

Inclusion criteria:

(1) Pregnant women with singleton pregnancy, term gestation, cephalic presentation, in active first stage of labor, the mothers who are booked cases ,had undergone routine antenatal check ups and all antenatal investigations are within normal limits .
(2) Cervical dilation >3 cm and <5 cm.
(3) ASA I and II mothers with no co-existing diseases like diabetes, hypertension, PIH, bronchial asthma, epilepsy, thyroid disorders, IHD, valvular heart disease, previous LSCS
(4) Age 18-35 years.
(5) Height >150 cm.
(6) primigravida
(7) BMI 18-25

Exclusion criteria:

1. Medical disorders and pregnancy associated disorders with ASA III and IV.
2. Spine abnormalities and local skin infections.
3. Coagulopathies.
4. CPD.
5. Preterm gestation.
6. Non reassuring NST

The study population consists of 60 parturient allocated into two groups, 30 in each group. The parturients satisfying the selection criteria were randomized by computer generated randomization table into two groups of thirty each – Group I and Group II. The randomization sequence was prepared in double-blinded cancelled manner. The study blinding was broken after the statistical analysis.

(1) Group I: receive intrathecal fentanyl 25µg+epidural 0.1% bupivaccaine 10 ml with 2µg of fentanyl/ml

(2) Group II: receive intrathecal fentanyl 25 µg +epidural 0.0625% bupivaccaine 10 ml with 2µg of fentanyl/ml

MONITORING:

1. Time of onset of analgesia
2. Level of sensory blockade.
3. Assessment of motor blockade.
4. Assessment of sedation.
5. Duration of analgesia.
6. Assessment of cardiovascular status and respiratory system
7. Complications/side-effects, if any.

1.Onset of analgesia: Time taken for achieving visual analog scale less than 3. The patient is asked to point to the position on the line between the faces to indicate how much pain they are currently feeling. The far left end indicates 'No pain' and the far right end indicates 'Worst pain ever'

2. level of sensory blockade: The level of sensory blockade will be

assessed every 15 minutes using spirit cotton for loss of cold sensation in the midclavicular line bilaterally from the nipple to the pubic symphysis.

3. assessment of motor blockade: Assessed by modified Bromage scale

4.assessment of sedation: Sedation was assessed using 5- point scale

5.duration of analgesia: Time interval from the onset of analgesia till the return of painful contraction (VAS more than 3) or till regression of sensory level to below T12. The parturients are observed for 15 minutes after delivery to assess pain relief.

6.Patient satisfaction score: 1-excellent 2-good 3-poor

Data were analysed using INSTAT 3 (Graph Pad Software, California, USA).Two sided independent student's t tests to analyse continuous data, Fisher's exact test and chi-square test for categorical data were used. P<0.05 was considered as statistically significant.

4. RESULTS

TABLE :1 Total number of epidural bolus doses (top-up): (student t test)

Group I	3.93± 0.640	P VALUE
Group II	3.77± 0.504	0.267

TABLE:2 TOTAL VOLUME OF LOCAL ANESTHETIC AGENT(students t test)

Group I	29.67± 3.198	P VALUE
Group II	28.83± 2.520	0.267

TABLE :3 TOTAL DOSE OF BUPIVACAINE(student t test)

Group I	29.67±3.198	P VALUE
Group II	18.02± 1.575	0.000

Mean of total number of epidural bolus doses used in group I was 3.93 with SD of 0.640. In group II Mean of total number of epidural bolus doses used was 3.77 with SD of 0.504. P value of 0.267 and was statistically in significant.Mean of total volume used for epidural analgesia in group I was 29.67 ml with SD of 3.198. In group II mean of total volume used for epidural analgesia used was 28.83 ml and SD of 2.520. P value of 0.267 and was statistically insignificant.Mean of total dosage of bupivacaine used in group I was 29.67 mg with SD of 3.198. In group II mean of total dosage of bupivacaine used was 18.02 with SD of 1.575. P value of 0.000 and was statistically very significant

TABLE :4 TOTAL DOSE OF FENTANYL(student t test)

Group I	59.33± 6.397	P VALUE
Group II	57.67± 5.040	0.267

TABLE : 5 TIME TO VAS<3(student t test)

Group I	125.67±44.62	P VALUE
Group II	124.167±41.07	0.8925

Mean of total dosage of fentanyl used in group I was 59.33 mg with SD of 6.397. In group II mean of total dosage of bupivacaine used was 57.67 with SD of 5.040. P value of 0.267 and was statistically insignificant..Mean of onset of analgesia (time to VAS <3) in group I was 125.67 seconds and SD of 44.62. In group II mean of onset of analgesia was 124.167 and SD of 41.07. P value of 0.8925 and was statistically insignificant.

TABLE :6 HEIGHT OF DERMATOME (Chi-square test)

	T8	T10	T9	pvalue
Group I	16(53.33%)	8(26.67%)	6(20%)	**0.5213**
GroupII	15(50%)	8(26.67%)	7(23.33%)	

TABLE :7 VAS (student's *t* test)

VAS	Group I	GroupII	P value
5min	1	1	
10min	1	1	
15min	1	1	
30min	1	1	
60min	1	1	
90min	1	1	
120min	1.80	2	0.460
150 min	1.83	1.70	0.596
180 min	1.20	1.33	0.456

Maximum dermatomal level of sensory blockade achieved in both groups was T8. 53.33 % in group I and 50 % % in group II had T8 level.26.67 % in group I and 26.67% in group II achieved T10 level. 20 % in group I and 23.33% in group II achieved T9 level. P-value 0.5213 and statistically insignificant.The above table shows VAS score changes. From the above table p-value of both the groups shows no statistically significant differences Pruritis was most commonly seen in both the groups. In group I (79.3%), group II (82.8%)TABLE :8

TABLE :8 -COMPLICATIONS

Complications	Group I	Group II
Pruritis	23 (76.67%)	24(80%)
none	7(23,33%)	6(20%)

TABLE :9 PATIENT SATISFACTION

Satisfaction	Group I	Group II
1	30	30
2	0	0
3	0	0

TABLE: 10 –SEDATION IN BOTH GROUPS

Sedation score	Group I	GroupII	P value
15min	0±0	0±0	1.000
30min	0.27±0.450	0.27±0.450	1.000
60min	0.27±0.450	0.27±0.450	1.000
90min	0.27±0.450	0.27±0.450	1.000
120min	0.27±0.450	0.27±0.450	1.000
150min	0.27±0.450	0.27±0.450	1.000
180min	0.23±0.430	0.17±0.379	0.527

5. DISCUSSION

The gold standard technique for providing labour analgesia is Neuraxial labour analgesia that provides effective pain relief for labouring women without compromising maternal and fetal safety. Inadequate education and preparation of parturient, fear of instrumental delivery and caesarean section makes it unpopular among obstetricians and parturients. Modern advancement in techniques , drugs and dosages, use of adjuvants, and monitoring makes it safer for parturients and anesthesiologists.Usage of low concentration of local anesthetics avoids motor blockade that otherwise may affect the course and the outcome of labour. Ultra minimal low dose local anesthetics selectively blocks the 'C' fibres which transmits pain. At such doses, there is no motor blockade. But lower concentration of local anesthetics may result in suboptimal and inadequate analgesia, if used alone. Adding opiods to this low dose local anesthetics makes it effective for labour analgesia.In our study, we gave labour analgesia with combined spinal epidural analgesia technique in 60 parturients .Each group had 30 parturients. In both the groups analgesia was initiated with intrathecal injection of fentanyl 25 µg . Epidural catheterization was done following spinal analgesia . Epidural analgesia was initiated with 10 ml of 0.1% bupivacaine with fentanyl 2 µg/ml in group I and in group II with 10 ml 0.0625 % bupivacaine with fentanyl 2µg/ml . We compared the quality of analgesia by using VAS score during labour analgesia and patients satisfaction at the end of delivery in both the groups .We also compared the other parameters like onset, degree and duration of both analgesia and motor blockade .There were no differences between the groups with respect to age, height and weight.Mean of baseline VAS in group I was 9.63and SD of 0.49. In group II mean of baseline VAS was 9.67 and SD of 0.48. P value of 0.7506 and was statistically insignificant. In a randomized study, Lyons et al[1] compared needle-through-needle and separate needle CSE in 100 patients undergoing caesarean section and Casati et al, randomly allocated, 120 non-

obstetric patients to needle through needle or separate needle CSE . They observed that there was lower spinal failure rate, with less hypotension and it took lesser time to perform in Separate needle CSE group. In this study we used separate needle CSE technique.[1] For the stage of early latent phase, Opioid alone may provide sufficient pain relief. But within 10 minutes of spinal injection, a low dose epidural infusion of bupivacaine 0.03–0.0625% with opioid may be started. Alternatively, the epidural component may be activated when necessary. In our study also we initiated labour analgesia with intrathecal fentanyl 25 µg followed by epidural catheter placement in L3-L4/L2-L3 space and catheter tip kept at T12/L1 level. Following spinal analgesia group I received 0.1% bupivacaine with fentanyl 2µg or group II received 0.0625% bupivacaine with fentanyl 2µg / ml. Mean of onset of analgesia (time to VAS <3) in group I was 125.67 seconds and SD of 44.62. In group II mean of onset of analgesia was 124.167 and SD of 41.07. P value of 0.8925 and was statistically insignificant. As in the both the groups analgesia was initiated with intrathecal fentanyl 25 µg, there was no statistically significant differences in onset. There was effective and rapid onset of pain relief in both the groups at around 2minutes.Maximum dermatomal level of sensory blockade achieved in both groups was T8. 53.33 % in group I and 50 % % in group II had T8 level.26.67 % in group I and 26.67% in group II achieved T10 level. 20 % in group I and 23.33% in group II achieved T9 level. P-value 0.5213 and statistically insignificant.This was comparable to the level achieved by Collis et al and cascio et al.[2] [3] [4] In our study no cases in both the groups showed motor blockade. All had Bromage score 0. There was no statistically significant differences in blood pressure, pulse rate, saturation in both the group. No statistically significant differences in Sedation score of both groups. Some patients showed mild drowsiness (score 1) mainly due to effective pain relief. In both the groups VAS was maintained with less than 3.In most cases VAS 3 usually coincide with the onset of 2nd stage of labour. Repeating the 10 ml of bupivacaine maintained the analgesia. Mean of total number of epidural bolus doses used in group I was 3.93 with SD of 0.640. In group II Mean of total number of epidural bolus doses used was 3.77 with SD of 0.504. P value of 0.267 and was statistically very significant. Mean of total volume used for epidural analgesia in group I was 29.67 ml with SD of 3.198. In group II mean of total volume used for epidural analgesia used was 28.83 ml and SD of 2.520. P value of 0.267 and was statistically insignificant. There was no difference between both the groups in volume requirement.Mean of total dosage of bupivacaine used in group I was 29.67 mg with SD of 3.198. In group II mean of total dosage of bupivacaine used was 18.02 with SD of 1.575. P value of 0.000 and was statistically very significant.Mean of total dosage of fentanyl used in group I was 59.33 mg with SD of 6.397. In group II mean of total dosage of bupivacaine used was 57.67 with SD of 5.040. P value of 0.267 and was statistically insignificant.76.67% in group I and 80 % in group II had experienced pruritus. In most of the women pruritus is mild and self limiting, not requiring any treatment, settles down over first hour of fentanyl administration. Some may responded to ondensetron 4mg IV

6.CONCLUSION

In conclusion both epidural 0.0625% bupivacaine and 0.1% bupivacaine groups provides good quality of labour analgesia. Using the ultra low dose concentration of bupivavaine 0.0625 % is not inferior, when compared to the low dose 0.1% of bupicavaine , but both are comparable in providing the good quality of analgesia. The dosage requirement was less in 0.0625% bupivacaine group than 0.1% group. Except pain and temperature, sensation like touch, uteriene contraction are preserved in all parturients. In both the groups no motor blockade was seen. Duration of labour was not prolonged by combined spinal epidural analgesia , but actually it decreases the duration of labour. The most frequent side effect associated with combined spinal epidural analgesia was pruritus which was also mild, transient and self-limiting

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