Original Research Paper

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RANDOMIZED DOUBLE BLIND STUDY ON OBSTERTIC AND FETAL OUTCOME WITH TWO DIFFERENT DOSES OF EPIDURALLY ADMINISTERED BUPIVACAINE IN COMBINED SPINAL EPIDURAL LABOUR ANALGESIA

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ABSTRACT Prospective randomized double blind study of combined spinal epidural labour analgesia for vaginal delivery with intrathecal fentanyl 25 µg +epidural 0.0625% bupivacaine 10 ml with 2µg of fentanyl/ml versus intra thecal fentanyl 25µg+epidural 0.1% bupivacaine 10 ml with 2µg of fentanyl/ml was planned to compare duration and progression of different stages labor and mode of delivery in both the techniques and Intra partum fetal heart rate monitoring and newborn evaluation with APGAR score to study the effect of them on obstetric and fetal outcome. Sixty patients were selected and divided into two groups Group I: received intrathecal fentanyl 25µg+epidural 0.1% bupivacaine 10 ml with 2µg of fentanyl/ml Group II: received intrathecal fentanyl 25 µg +epidural 0.0625% bupivacaine 10 ml with 2µg of fentanyl/ml. Partogram, fetal tocography and APGAR score was recorded in both groups . Duration of labour was not prolonged by combined spinal epidural analgesia, but actually it decreases the duration of labour All babies were delivered by normal vaginal delivery except one in group I which was delivered by forceps delivery. No parturients in both the groups underwent caesarean delivery. No babies required resuscitation and neonatal intensive care unit admission.

KEYWORDS : Labour analgesia, Partogram, Fetal tocography, APGAR score

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 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.

2.AIMS

1. To compare duration and progression of different stages labor and mode of delivery in both the techniques
2. Intra partum Fetal heart rate monitoring and newborn evaluation with APGAR score

3. MATERIALS &METHODS:

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. After taking the written informed consent, Only those who fulfill the following criteria were 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 parturients 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

PREPARATION OF THE PARTURIENT:

- prepared as per the routine preparation done for delivery, in addition to preparation of back to perform epidural block.
- The onset of active labour, degree of cervical dilatation and the adequacy of pelvis for vaginal delivery was assessed by attending obstetrician, before performing block.
- The patient examined CVS, RS system in detail and a base line pulse rate, BP, RR were recorded.
- An intravenous line was stared on non dominant hand with an 18 G cannula.
- The parturient preloaded with 500- 1000 ml 0f Ringer lactate solution

All equipment needed for airway management and resuscitation of the mother and baby was kept ready before performing block.

PREPARATION OF EPIDURAL BUPIVACAINE:

The epidural drug preparation will be done by duty assistant professor who will prepare it according to the group allocation for which I will be blinded.

- 2 ml of 100mcg fentanyl (50 mcg/ml) diluted with 3 ml of normal saline which gives 20mcg /ml fentanyl.
- For group I 2ml of 0.5 % bupivacaine mixed with 20 mcg of prepared inj. fentanyl (1ml) and 7ml of normal saline which gives 0.1% bupivacaine with fentanyl 2 mcg/ml.
- For group II 1.25ml of 0.5% bupivacaine mixed with 20 mcg of prepared inj.fentanyl (1ml) and 7.75ml of normal saline which gives 0.0625% bupivacaine with fentanyl 2 mcg/ml.

PERFORMING THE BLOCK:

We used separate needle CSE technique for this study. We initiated subarachanoid blockade followed by epidural catheter insertion at higher space.

1. sitting/left lateral position
2. aseptic precautions

3. ideal space L3-L4/L4-L5
4. local infiltration with 1 cc of 2% lignocaine in the L3-L4/L4-L5 for both spinal epidural needle placement.
5. intrathecal fentanyl 25 µg given with 25 g quincke needle by insulin syringe usually in L4-L5 space. If it fails we tried it in higher space.
6. bevel directed upward, midline approach with Tuohy needle, identification of epidural space by loss of resistance with air technique . Epidural placement is usually done in one space above the spinal injection.
7. catheter placed 3-5 cm in epidural space
8. after negative aspiration for blood and CSF, the epidural catheter secured. I will omit the traditional test dose. But I will prefer to give the each therapeutic dose of local anesthetic slowly, 5 ml incrementally , cautiously, I will consider each increment dose of the therapeutic dose as the test dose. These precautions should be followed by me with all bolus injections of local anesthetic through an epidural catheter.
10. turned to her back and left uterine displacement by using a wedge under right buttock
11. 10 ml of 0.0625 %bupivacaine with 2 µg/ml fentanyl for group II or 10 ml of 0.125% bupivacaine with 2µg/ml fentanyl for group I given epidurally.
12. after 60 minutes or after recurrence of pain or after two segment regression whichever is earlier, 5cc of above concentration will be given epidurally

MONITORING:

1.progress of labour

- The progress of labour is observed closely after instituting block by partograph.
- The frequency and intensity of uterine contractions, dilation and effacement of cervix descent of presenting part and foetal heart rate are periodically by the obstetrician.
- The requirement for instrumental deliveries or Caesarean section and the indications for the same also noted.

2. Fetal monitoring:

- The foetal heart rate is monitored by cardiotocograph.
- Rate less than 100/ minute is taken as bradycardia and rate of more than 160/minute is taken as tachycardia.
- At birth, the APGAR score of the neonate at 1and 5th minutets is used to assess the neonatal well being. Any neonate with an apgar score of less than 7 will be resuscitated with suctioning , mask ventilation and if needed, intubation and ventilation with 100% oxygen.

STATISTICAL ANALYSIS: 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 NO 1:CERVICAL DILATATION

	4cms	5cms	p value
Group I	18 (60%)	12(40%)	0.7948
Group II	16 (53.33%)	14 (46.67%)	

TABLE NO 2 : DURATION OF ACTIVE PHASE OF FIRST STAGE OF LABOUR

GROUP I	143.03± 30.948	P value
GROUP II	137.17± 23.878	0.414

TABLE NO 3 DURATION OF SECOND STAGE

Group I	19.63±5.102	P VALUE
Group II	19.90± 5.081	0.840

TABLE NO 4 :TOTAL DURATION OF DELIVERY

Group I	162.67± 31.422	P VALUE
Group II	157.07± 24.653	0.446

TABLE NO 5 : FETAL HEART RATE

Fetal heart rate	Group I	Group II	P VALUE
baseline	132.67± 8.293	133.47±8.850	0.719
5min	131.80±5.365	130.80±4.444	0.435
10min	131.20±6.820	128.67±6.177	0.137
15min	131.73±6.943	130.87±7.001	0.632
30min	134.93± 7.606	134.13± 6.947	0.672
60min	136.20±7.453	138.13±5.823	0.268
90min	134.47±8.924	134.73±7.817	0.902
120min	134.80±7.213	132.40±7.323	0.206

FIGURE NO 1: FETAL HEART RATE

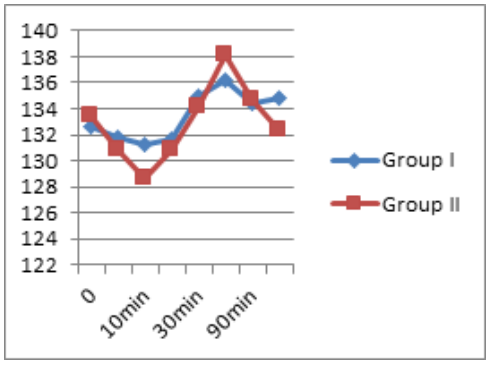


TABLE NO 6: OBESTERTIC OUTCOME

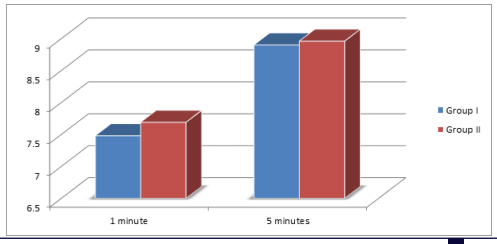
outcome	Group I	Group II
Normal vaginal delivery	29	30
forceps	1	0
LSCS	0	0

60% parturients in group I and 53.33% of group II had cervical dilatation of 4 cm. 40 % parturients in group I and 46.67% of group II had cervical dilatation of 5 cm. p-value of 0.7948 which is not statistically significant. Mean duration of active phase of 1st stage of labour in group I was 143.03 minutes with SD of 30.948. In group II mean duration of active phase of 1st stage was 137.17 minutes with SD of 23.878. P value of 0.414 and was statistically insignificant .Mean duration of 2nd stage of labour in group I was 19.63 minutes with SD of 5.102. In group II mean duration of 2nd stage was 19.90 minutes with SD of 5.081. P value of 0.840 and was statistically insignificant**.**Mean total duration of labour in group I was 162.67 minutes with SD of 31.422. In group II mean total duration of labour was 157.07 minutes with SD of 24.653. P value of 0.446 and was statistically insignificant**.** In both groups all babys delivered by normal vaginal delivery except in Group I two baby were delivered by forceps delivery. one baby delivered by forceps delivery after normal progress due to undiagnosed three times cord around the neck which was excluded from the study. No other case underwent LSCS or Forceps delivery. At 1 minute In group I mean of APGAR score was 7.48 and SD was 0.508. In group II mean was APGAR score 7.69 and SD was 0.471. p value of 0.114 and was statistically insignificant. At 1 minute In group I mean of APGAR score was 8.90 and SD was 0.309. In group II mean was APGAR score 8.96 and SD 0.185. p value of 0.309 and was statistically insignificant.

TABLE NO 7:APGAR SCORE

	Group I	Group II	P Value	Significance
1 minutes	7.48±0.508	7.69±0.471	0.114	NS
5 minutes	8.90±0.309	8.96±0.185	0.309	NS

FIGURE NO 2: COMPARISION OF APGAR SCORE BETWEEEN TWO GROUPS



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 insuboptimal 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/mlWe compared the onset, degree and duration of both analgesia and motor blockade , the duration of first and 2nd stage of labour, progress and outcome of labour, fetal heart rate changes, outcome of newborn by APGAR score and complications between both the groups.There were no differences between the groups with respect to age, height and weight statistically insignificant. Labour analgesia was initiated in both the groups between 4-5 cms of cervical dilatation. 60% parturients in group I and 53.33% of group II had cervical dilatation of 4 cm. 40 % parturients in group I and 46.67% of group II had cervical dilatation of 5 cm . p-value of 0.7948 which is not statistically significant. In a randomized study, Lyons et al compared needle-through-needle and separate needle CSE in 100 patients undergoing caesarean section[1] 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[2] . In this study we used separate needle CSE technique. Fetal heart rate changes in both groups were within normal limits. p-value of both the groups shows no statistically significant changes. During second stage to give effective analgesia all parturients in this study required initial 10 ml of local anesthetic bolus which gave effective pain relief even during episiotomy. This was not influenced by positioning of patient, mainly depended upon the volume.Merry A Fet al, .Park WY et al, .Erdemir HA et al studies shows that there was inconsistent results with sitting position during epidural drug administration but increasing the volume of local anesthestic provided effective pain relief [3,4,5]during 2nd stage of labour. Amit.G.Bhagwat et al concluded that when compared with epidural technique, CSE technique is associated with more rapid cervical dilation and shorter duration of labour[6] Lawrence C Tsen et al, concluded that CSE is associated with more rapid cervical dilation compared with epidural analgesia[7] . both the studies were conducted in nulliparous women. In our study CSE is associated with more cervical dilatation and shorter duration of labour. Mean duration of active phase of 1st stage of labour in group I was 143.03 minutes with SD of 30.948. In group II mean duration of active phase of 1st stage was 137.17 minutes with SD of 23.878. P value of 0.414 and was statistically insignificant Mean duration of 2nd stage of labour in group I was 19.63 minutes with SD of 5.102. In group II mean duration of 2nd stage was 19.90 minutes with SD of 5.081 . P value of 0.840 and was statistically insignificant Mean total duration of labour in group I was 162.67 minutes with SD of 31.422. In group II mean total duration of labour was 157.07 minutes with SD of 24.653. P value of 0.446 and was statistically insignificant The duration of first stage ,second stage and total duration labour was shorter because of decreased local anesthetic exposure. Effective and rapid analgesia reduces the level of epinephrine (a tocolytic) which may stimulate the uterine contraction. The duration of labour may also be shortened by active management of labour like early amniotomy, use of oxytocin both in early and later stage of labour etc. Most studies shows that the incidence of emergency cesarean section delivery is lesser in CSE labour analgesia than after conventional epidural analgesia[8,9] In both groups all babies were delivered by normal vaginal delivery except in Group I two baby were delivered by forceps delivery. One baby delivered by forceps delivery after normal progress due to undiagnosed three times cord around the neck which was excluded from the study. No other case underwent LSCS or Forceps delivery. At 1 minute In group I mean of APGAR score was 7.48 and SD was 0.508. In group II mean was APGAR score 7.69 and SD was 0.471 . p value of 0.114 and was statistically insignificant. At 1 minute In group I mean of APGAR score was 8.90 and SD was 0.309 . In group II mean was APGAR score 8.96 and SD 0.185 . p value of 0.309 and was statistically insignificant.

6.CONCLUSION

In conclusion both epidural 0.0625% bupivacaine and 0.1% bupivacaine groups provides good quality of labour analgesia.. Duration of labour was not prolonged by combined spinal epidural analgesia, but actually it decreases the duration of labour All babies were delivered by normal vaginal delivery except one in group I which was delivered by forceps delivery. No parturients in both the groups underwent caesarean delivery. No babies required resuscitation and neonatal intensive care unit admission.

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