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# EPIDURAL ANALGESIA FOR LABOUR PAIN: EFFECT ON LABOUR, DELIVERY AND NEONATAL OUTCOME OF 0.125% BUPIVACAINE VS 0.125 % LEVOBUPIVACAINE

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## ABSTRACT

**Introduction:** Bupivacaine provides excellent analgesia for labour and delivery and remains the most widely used epidural local anaesthetic in obstetric anaesthesia. The newer local anaesthetics are significantly less cardio-toxic and neurotoxic than bupivacaine.

**Aims:** To compare low dose levobupivacaine and bupivacaine in same concentration during epidural technique regarding efficacy of analgesia.

**Material and Methods:** 60 parturients were randomly allocated to two groups of 30 each: GROUP B-received an initial epidural dose of 15 ml 0.125% bupivacaine with 3 mcg/ ml fentanyl and GROUP L-received an initial epidural dose of 15 ml 0.125% levobupivacaine with 3mcg/ ml fentanyl. Assessment of pain relief were carried before epidural injection and then at 10min interval for first 30mins and at hourly interval. Motor blockade was assessed using a modified bromage scale.

**Results:** 1) Both the groups provided equivalent labour analgesia and maternal satisfaction. 2) Bromage score >=1 was observed in 4 patients in group B and 2 patients in group L.3) Similar distribution of highest level of cutaneous sensory loss in pin prick was observed in both groups($p>0.05$). 4) The total dose of bupivacaine was slightly less than levobupivacaine but statistically insignificant. The total dose of fentanyl was also lower in group B but was statistically insignificant($p>0.05$). 5). There was no significant difference between the two groups regarding - the incidence of pruritus, hypotension, backache, vomiting, shivering. Pruritus was noted in 5 parturients in group L compared to 4 in Group B ($p>0.05$).

**Conclusion:** Both the regimes were equally effective in providing ambulatory labour analgesia with equivalent maternal satisfaction and neonatal outcome.

## KEYWORDS :

## INTRODUCTION

The delivery of a healthy new-born into the arms of a conscious and pain free mother is one of the most exciting and rewarding moments in anaesthesia. It has been suggested that confining women to bed during labour may cause the labour to be longer and more painful, with an increase in abnormal presentation, instrumental deliveries and fetal distress (Mendex et al 1975, Flynn et al 1978).The "walking epidural" first appeared in the early 1990s. In the first versions of the walking epidural, the combined spinal epidural (CSE) technique was used. Walking or ambulatory extradural labour analgesia is a novel approach to painless labour. It abolishes pain without affecting other sensations such as desire to push, to pass urine spontaneously and to allow movement in bed or normal walking. Various reports have suggested an association between an upright position and shorter labour. (Mitre .et al, Lupe PJ et al, Mentzer et al).

Lumbar epidural analgesia offers a safe and effective method of pain relief during labour. Low doses of local anaesthetic or opioid combinations are administered to provide a continuous T10-L1 sensory block during the first stage of labour. *Bupivacaine* provides excellent analgesia for labour and delivery and remains the most widely used epidural local anaesthetic in obstetric anaesthesia. The newer local anaesthetics are significantly less cardio-toxic and neurotoxic than bupivacaine. *Levobupivacaine*, a new amide local anaesthetic, seems to be equally as potent as racemic bupivacaine, but some studies have found a trend toward differences in onset and duration of sensory or motor block.

## AIMS AND OBJECTIVES

The *primary* aim was to compare low dose levobupivacaine and bupivacaine in same concentration during epidural technique regarding efficacy of analgesia. *Secondary* objectives were to compare the drugs regarding motor blockade and ambulation, progress of labour and mode of delivery, adverse effects (both maternal and fetal), neonatal outcome and patient satisfaction.

## REVIEW OF LITERATURE

Epidural analgesia was first reported by Graffangino and seyler (1935). Alexander et al, 1998 performed a posthoc analysis of 199 patients receiving epidural analgesia to compare the effects of epidural versus narcotic analgesia on labour. They concluded that epidural analgesia decreased uterine performance during oxytocin stimulated labour, resulting in an increase in duration of the first and second stages of labour. Meister et al, 2000 in a comparison of epidural analgesia with 0.125% Ropivacaine with Fentanyl Versus 0.125% Bupivacaine with Fentanyl during labour found that Ropivacaine 0.125% with fentanyl 2 pg/mL produced similar labour analgesia with significantly less motor block than an equivalent concentration of bupivacaine/fentanyl.

Beilin Yaakov et al, 2007 in a study concluded that bupivacaine, ropivacaine and levobupivacaine all confer adequate labour epidural analgesia, with no significant influence on mode of delivery, duration of labour, or neonatal outcome. Atienzer M.C. et al, 2008 in a randomized comparison of levobupivacaine, bupivacaine and ropivacaine with fentanyl, for labour analgesia studied102 nulliparous parturient in early labour. They were randomly assigned to receive one of three continuous epidural infusion regimens: levobupivacaine 0.125%, bupivacaine 0.125% or ropivacaine 0.2%, all with fentanyl 1 pg/mL at 8 mL/h. All three regimens were effective during first stage of labour although pain scores were higher in those receiving levobupivacaine. Motor block was greater with bupivacaine than with levobupivacaine.

*Bupivacaine* is an amide local anaesthetic commonly used. Its long duration of action, differential sensory to motor block and

relative lack of tachyphylaxis make it a popular choice. The placental transfer of bupivacaine is governed by two factors: the degree of ionization at physiologic pH and extent of protein binding. Bupivacaine has a pKa of 8.05 (highly ionized at. physiologic pH) and it is 95% protein bound; thus it has limited transfer to the placenta when compared with other local anaesthetics. Bupivacaine consists of two stereoisomers, S- and R+, and is marked as racemic mixture of these isomers. When separated, the R component was found to contribute to bupivacaine's unwanted toxicity. This finding led researchers to develop the use of S isomer for clinical practice, which resulted in the introduction of ropivacaine (the S isomer of the propyl homolog of bupivacaine) and levobupivacaine (the S isomer of bupivacaine).

*Levobupivacaine* has a safety margin of 1.3, which means toxic effects are not seen until the concentration rises by 30%. The concentration necessary to produce cardiac and neurotoxicity is higher for levobupivacaine than for racemic bupivacaine.

## MATERIAL AND METHODS

After obtaining written informed consent and hospital ethics committee approval, this prospective double blind randomized controlled study was conducted in S.N. Medical College Agra. 60 parturients, ASA grade 1/2 with 37-41 weeks of pregnancy in active labour with no obstetrical/medical complication requesting painless labour were included in the study.

***Inclusion Criteria:***

1. Both primipara and multipara parturients.
2. Patient in active labour-uterine contractions 2/10 minimum lasting for 30-40 sec and cervical dilatation equal to or more than 4 cm.
3. Term cephalic singleton pregnancy.
4. Informed consent.

The parturients were randomly allocated to two groups of 30 each: GROUP B-received an initial epidural dose of 15 ml 0.125% bupivacaine with 3 mcg/ ml fentanyl and GROUP L-received an initial epidural dose of 15 ml 0.125% levobupivacaine with 3mcg/ ml fentanyl. Both groups received further epidural boluses on patient demand with no background infusion.

***Exclusion criteria:*** Any presentation other than cephalic, cephalopelvic disproportion, bleeding disorder, antepartum haemorrhage,any neurological disease,morbid obesity, patient not giving consent.

In antenatal period, all parturients were instructed about verbal analogue pain scores (VAPS,0-100 scale:0=no pain, 100=worst pain). The study period commenced after the epidural injection and finished at the delivery of the baby. The time from initial epidural injection to first painless contraction was taken as onset of epidural analgesia. Duration of epidural analgesia was defined as the interval between epidural injection and request for epidural top-up.

Assessment of pain relief were carried before the epidural injection and then at 10min interval for first 30mins and at hourly interval thereafter as follows

1. verbal analogue pain scores
2. verbal rating pain scores

The verbal analogue pain score was recorded as VAPS,0-100: 0=no pain,100=worst pain ever experienced. The four point verbal rating score included (0=no pain, pressure or tightening; 1=aware of tightening or pressure but not painful; 2=tolerable pain, not distressing; 3=distressing pain or pressure). The numbers of recordings of each verbal rating pain score were summed from all women in each study group to produce a total for each of the four pain scores. This was then expressed as a percentage of the total number of pain assessments for each study group [cumulative analgesia score ((%)]. The highest dermatomal level of sensory block was assessed using loss of pinprick sensation in the midclavicular line before administration of epidural analgesia at 5, 10,20,30,45,60min and every 30 min thereafter until delivery.

Motor blockade was assessed using a modified bromage scale (0=able to straight leg raise against resistance, i.e. no detectable motor block,1=unable to straight leg raise but able to flex knee;2=unable to flex knee but able to flex artkle;3=unable to move hip, knee or ankle). The FHR and fetal cardiotocogram (CTG) were recorded continuously throughout the study period. The occurrence of late or variable decelerations or fetal bradycardia of less than 110 beats/min was recorded as significant.

Statistical analysis were performed by using SPSS software version 20 (SPSS inc., Chicago, IL, USA) and included student's t-test, chi-square and ANOVA tests as appropriate.

## OBSERVATIONS

***Table-1 Shows Onset And Duration Of Epidural Analgesia (Initial Dose)***

| | GROUP B | | GROUP L | | P |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | VALUE |
| ONSET (MIN) | 15.40 | 2.568 | 15.70 | 2.961 | .677 |
| DURATION (MIN) | 113.43 | 20.592 | 110.67 | 25.158 | .643 |

***Table 2 Shows Verbal Analogue Pain Scores***

| TIME (MIN) | GROUP B | | | GROUP L | | | P |
|---|---|---|---|---|---|---|---|
| | Mean | SD | n | Mean | SD | N | VALUE |
| (BASELINE) 0 | 85.73 | 3.300 | 30 | 84.73 | 2.962 | 30 | .223 |
| 10 | 22.33 | 1.709 | 30 | 23.13 | 1.716 | 30 | .076 |
| 20 | 20.50 | 1.607 | 30 | 20.63 | 1.866 | 30 | .773 |
| 30 | 20.03 | 1.790 | 30 | 20.33 | 1.605 | 30 | .497 |
| 60 | 20.57 | 1.591 | 30 | 20.70 | 1.622 | 30 | .749 |
| 120 | 20.57 | 1.695 | 30 | 20.43 | 1.633 | 29 | .758 |
| 180 | 20.77 | 1.591 | 26 | 20.50 | 1.869 | 26 | .557 |
| 240 | 20.63 | 1.671 | 20 | 20.03 | 1.821 | 20 | .081 |
| 300 | 20.60 | 1.545 | 19 | 20.53 | 2.013 | 18 | .886 |
| 360 | 21.17 | 1.840 | 19 | 20.40 | 1.673 | 18 | .097 |

***Table-3 Cumulative Analgesia Score***

| PAIN SCORE | GROUP B | GROUP L | CHI- SQUARE | P-value |
|---|---|---|---|---|
| 0 | 38 | 50 | 2.92 | 0.087 |
| 1 | 48 | 38 | 2.04 | 0.153 |
| 2 | 11 | 9 | 0.22 | 0.637 |
| 3 | 3 | 3 | | |

***Table-4 Shows Number Of Top Up Doses***

| NO OF TOP UP | GROUP B | GROUP L | P VALUE |
|---|---|---|---|
| 1 | 4 | 5 | P>0.05 |
| 2 | 17 | 15 | P>0.05 |
| 3 | 9 | 10 | P>0.05 |

***Table-5 Shows Maximum Degree Of Motor Block Measured On Modified Bromage Scale***

| Modified bromage score (max) | Group B | Group L | P Value |
|---|---|---|---|
| 0 | 26 | 28 | P>0.05 |
| 1 | 4 | 2 | P>0.05 |
| 2 | 0 | 0 | |
| 3 | 0 | 0 | |
| Bromage score>=1 | 4 | 2 | P>0.05 |

*Table-6 Shows Duration Of Stages Of Labour*

| | GROUP B | | GROUP L | | P |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | VALUE |
| Ist stage of labour (min) | 277.23 | 46.33 | 276.40 | 41.571 | .948 |
| 2nd stage of labour (min) | 48.50 | 9.198 | 49.73 | 9.392 | .609 |

*Table-7 Shows Mode Of Delivery*

| MODE OF DELIVERY | GROUP B | | GROUP L | | P VALUE |
|---|---|---|---|---|---|
| | N=30 | percentage | N=30 | percentage | |
| Spontaneous vaginal delivery | 28 | 93.33% | 29 | 96.67% | p>0.05 |
| Caesarean | 2 | 6.67% | 1 | 3.33% | p>0.05 |
| instrumental | 0 | 0.00% | 0 | 0.00% | p>0.05 |

*Table-8 Shows Maternal Side Effects And Complications*

| | GROUP B | GROUP L |
|---|---|---|
| HYPOTENSION | 0 | 0 |
| NAUSEA/VOMITING | 0 | 0 |
| PRURITUS | 4 | 5 |
| BACKACHE | 2 | 2 |
| SHIVERING | 3 | 4 |
| URINARY RETENTION | 0 | 0 |
| FETAL BRADYCARDIA | 0 | 0 |
| RESPIRATORY DEPRESSION | 0 | 0 |
| NEUROLOGICAL DEFICIT | 0 | 0 |

## DISCUSSION

In the present double blind random study, sixty parturients were allocated to two groups. Group B received an initial epidural 15ml bupivacaine 0.125% with fentanyl 3mcg/ml. While Group L received 15ml Levobupivacaine 0.125% with fentanyl 3mcg/ml. Both groups received on demand boluses thereafter. The parturient had an average age comparatively less than western studies. Similarly mean height as well as mean weight was significantly less than other studies (Breen 1993, Cohen 2000, Hepner 2000). No statistical differences were detected between the groups with respect to age, weight, height, gestational age, parity or cervical dilation prior to block.

Fentanyl doses of 3 mcg/ml were chosen by using the information from the fentanyl and bupivacaine study, which suggested that an effect would be difficult to detect at 1 mcg/ml and that 4 mcg/ml would be associated with significant pruritus (Lyons G et al 1997). Epidurally we decided to use the same concentration 0.125 % bupivacaine and levobupivacaine to test the clinical relevance with the analgesic potency of epidural bupivacaine and levobupivacaine in parturients in early labour, as was directly compared in studies (Burke et al 1999, Convery et al 1999 and Lm et al 2004, Li Zhong et al 2010).

When motor block as measured by Bromage score was the primary outcome, Convery et al found less motor block with levobupivacaine when the concentrations ranging between 0.0625% and 0.2% were used. Bupivacaine, ropivacaine or levobupivacaine seem to be very similar as to motor block, mode of delivery and duration of labour (Sah N 2007, Camorcia M 2003, Beilin Y 2007). It was not surprising that 0.125 % bupivacaine and 0.125 % Levobupivacaine were found equianalgisic in our study.

The time from epidural injection to the first painless contraction was taken as the onset of analgesia. We found a similar time of onset in both the groups (Group B mean 15.40 ± 2.568, Group L mean 15.70 ±2.961). We found a similar duration of epidural analgesia in both the groups (group B, mean 113.43 ±20.59, group L mean 110.67±25.16). These results were comparable to the findings of other workers (Burke 1999, Convery 1999, Chang and Chiu 2004).

The total dose of bupivacaine was slightly less than levobupivacaine but statistically insignificant. The total dose of fentanyl was also lower in group Bupivacaine but was statistically insignificant. The number of supplemental oblique rescue analgesic doses were similar in both the groups signifying a similar incidence of breakthrough pain (p>0.05).

Detectable motor block i.e. inability to straight leg raise against resistance occurred in two patients in levobupivacaine group compared with four patients in bupivacaine group but this difference was statistically insignificant (p>0.05). However the minimum effective local anaesthetic concentration of levobupivacaine for motor block (MMLAC) was significantly greater than that of bupivacaine in study of Lacassie and Columb 2003 indicating levobupivacaine is less potent at motor block than bupivacaine.

The modified bromage scale scoring system used in the study, however is not highly sensitive and may not have uncovered slight differences between groups, if they excisted. A quantitative method of comparing motor block repeated maximal isometric contraction, as described by Axelsson (1985). This procedure however is more difficult to use and unfamiliar to most anaesthesia providers. We selected the current method because it is simple and clinically useful in detecting gross differences in motor block.

Proprioception was intact in all cases. Thus in this context our finding of reduced leg weakness, using low and identical concentrations of levobupivacaine and bupivacaine when combined with fentanyl, suggest that they can be used interchangeably for walking epidural.

Sensory block in the present study was tested using loss of pin prick sensation. The choice of this method instead of others (such as loss of sensation to eyes, pain perception, tetanic twitch or chemical irritation with capsaicin) was based on Hacking study which proved the reliability and easy application of pin prick method.

A similar distribution of highest level of cutaneous sensory loss to pin prick in the midclavicular line, was observed in both groups (p>0.05). There was no significant difference among the groups regarding oxytocin supplementation, mode of delivery. More than 90% parturients in each group had spontaneous vaginal delivery. Our results on duration of stages and mode of delivery were also supported by two previous studies (Bellin Y et al 2007, Li Zhong W 2010)

A particular concern about ambulatory parturients recieving labour analgesia is orthostatic hypotension. In our study both the groups had haemodynamic stability and this can be contributed to low concentration of both study solution.

In our study there was no accidental dural puncture in any group. There was no significant difference between the two groups in the incidence of pruritus, hypotension or back ache, vomiting, shivering. Pruritus was noted in 5 patients in group L compared to 4 in group B (P>0.05) but it did not required treatment. No patient required urinary catheterization.

All parturients were interviewed about acceptance and views on labour technique. We found that parturients acceptance was excellent to good in more than 99% in both groups.

## SUMMARY & CONCLUSION

1. Both the groups were comparable with respect to age, height, weight, gestational age, oxytocin use and cervical dilation prior to block.
2. The time of onset and duration of analgesia were comparable in both the groups.

3. Both the groups provided equivalent labour analgesia and maternal satisfaction. The number of supplemental oblique rescue analgesic doses was similar in both the groups signifying a similar incidence of breakthrough pain (p.0.05).
4. Bromage score >=1 was observed in 4 patients in group B and 2 patients in group L. It lasted transiently and did not affect ambulation.
5. Similar distribution of highest level of cutaneous sensory loss in pin prick was observed in both groups(p>0.05).
6. The total dose of bupivacaine was slightly less than levobupivacaine but statistically insignificant. The total dose of fentanyl was also lower in group B but was statistically insignificant(p>0.05).
7. The two groups had comparable and similar duration of first and second stages of labour.
8. There was no significant difference in the two groups regarding mode of delivery. More than 90 % parturients in each group had spontaneous vaginal delivery. The chances of caesarean delivery were not increased in any group.
9. There was no significant difference between the two groups regarding - the incidence of pruritus, hypotension, backache, vomiting, shivering. Pruritus was noted in 5 parturients in group L compared to 4 in Group B (p>0.05). But it did not require treatment.
10. Neonatal outcome was good and comparable in both the groups.

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