COMPARATIVE CLINICAL STUDY BETWEEN EPIDURAL AND COMBINED SPINAL EPIDURAL ANALGESIA ON LABOUR WITH 0.125% BUPIVACAINE AND 20µG FENTANYL
Narendra Babu M. C, Sreeraghu G. M, Sanjay M. V, Dwideep Chandra, Sreeharsha S

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ABSTRACT: OBJECTIVES: The present study was planned as a prospective study with the following objectives: 1. To evaluate the efficacy of 0.125% bupivacaine with 20 µg fentanyl in relieving parturition pain with lumbar epidural and combined spinal epidural analgesia. 2. To compare the impact of lumbar epidural and combined spinal epidural technique on maternal satisfaction for pain relief, progress of labor, mode of delivery, neonatal outcome. RESULTS: The two groups were similar with respect to age distribution, height, weight, BMI of the parturients (table 1 & 2). The onset of analgesia was 1.98±0.33 min in group CSE and 5.00±1.64 min in group E (table 3). Peak action of analgesia was 4.15±0.41min in CSE group and 9.87±1.97 min in group E. The onset and peak of analgesia was faster in group CSE and is statistically significant with p<0.001 (table 4). VAS score was statistically similar in both groups (table 5). Motor blockade assessed by modified Bromage scale, there was no motor blockade in any case in either of the groups (table 6). In group CSE the pulse rate changed from basal 82.27±9.7 of beats per minute to 81.5±9.75 during first stage and 86.83±8.92 during the second stage. In group E the pulse rate changed from basal 81.53±7.43 of beats per minute to 83.67±8.65 during first stage and 87.73±10.02 during the second stage. This was comparable in both the groups and is statistically insignificant (table 7). The variations in blood pressure noted in SBP in 1st and 2nd stage were not statistically significant in both the groups (table 8). The variations noted in DBP were statistically significant in both groups. Parturients in group CSE had a basal DBP of 76mmhg which dropped to 73mmhg in first stage and 72mmhg in 2nd stage. In epidural group basal DBP was 78mmhg which dropped to 76.6mmhg in the 1st stage. In 3rd stage mean DBP was 78mmhg which was similar to the basal DBP. The basal DBP was significantly less in 2nd stage in CSE group compared to group E with respect to basal levels. This is statistically significant with p =0.001 (table 9). Mean cervical dilatation in group CSE was 3.93±0.58 cm and 3.86±0.57cm in group E which was statistically similar in both the groups (table 10). Mean duration of labor were not statistically significant for 1st and 2nd stages in the two groups. Duration of third stage was more in epidural group compared with CSE group and this was statistically significant (table 11). 63.3% of parturients in both the groups required only 1-2 top ups which was given on demand or when patient perceived pain .No top up was given in 16.7% and 10% parturients in group CSE and E respectively. Maximum top ups given was 5-6 for three parturients in CSE group and none in other group. Mean top up needed in CSE group was 1.70±1.46 and 1.67±0.99 in group E which was statistically insignificant (table 12). Mean interval between the time of analgesia and the time of delivery is 3.53±1.62 hrs. in group CSE and 3.48±1.18 hrs. in group E showing no statistical significance (table 13). CONCLUSION: We conclude that, the analgesia provided during labor by both the techniques was satisfactory and comparable. The onset and peak of analgesia was faster in CSE than epidural analgesia. The quality and duration of analgesia were comparable in both the groups. The drop in DBP in 2nd stage of labor
in group CSE was significant. The duration of 3rd stage of labor in group CSE was significantly shortened. The incidence of pruritus is more in CSE than epidural technique. There is no motor blockade in both the groups and comparable. Fetal outcome is comparable in both the groups. In conclusion the onset and peak of analgesia is faster in CSE than epidural technique but is associated with higher incidence of pruritus. The quality, duration of analgesia, motor blockade and fetal outcome are all comparable in both the groups.

KEYWORDS: Combined spinal epidural, fentanyl, Bupivacaine.

INTRODUCTION: Pain in labour is an extremely agonising experience for most women. Various methods have been tried since time immemorial to alleviate this pain. However, this endeavour did not receive much support till the late 19th century, with analgesia for labour being opposed for both medical and religious reasons. It was also believed that pain had a biological value and attempts to abolish it would be detrimental to both the mother and the foetus. However, the recognition of various physiological disturbances that can occur due to unrelieved labour pain brought about a change in this thinking. In view of this, the concept of labour analgesia came to be widely accepted.

OBJECTIVES:
The present study was planned as a prospective study with the following objectives:
1. To evaluate the efficacy of 0.125% bupivacaine with 20 µg fentanyl in relieving parturition pain with lumbar epidural and combined spinal epidural analgesia.
2. To compare the impact of lumbar epidural and combined spinal epidural technique on maternal satisfaction for pain relief, progress of labour, mode of delivery, neonatal outcome.

MATERIALS AND METHODS:
Source of Data: Pregnant women in active labor (cervical dilatation more than 3cm with good uterine contractions) with term gestation with cephalic presentation opting for painless labor admitted in Obstetrics & Gynecology Department of Kempegowda Institute of Medical Sciences Hospital, Bangalore.

Method of collection of data:
Inclusion criteria:
1. Pregnant women with singleton pregnancy, term gestation, cephalic presentation, in active first stage of labour.
2. Cervical dilation >3 cm and <5 cm.
3. ASA I and II.
4. Age 18-35 years.
5. Height >145 cm.
6. BMI 18-25.

Exclusion criteria:-
1. Unwilling subjects.
2. Medical disorders and pregnancy associated disorders with ASA III and IV.
4. Coagulopathies.
5. CPD.
6. Preterm gestation.
7. No reassuring NST.
The study population consisted of 60 parturients. They were divided into 2 groups of 30 each. Group I received combined spinal epidural analgesia. Group II received epidural analgesia.

Preparation of the Parturient: The parturient was prepared as per the routine preparations done for delivery. In addition, preparation of the back was done for performing the epidural block. The onset of active labour, degree of cervical dilatation and adequacy of the pelvis for vaginal delivery were all assessed by the attending obstetrician before institution of the epidural block. The patient was examined and a baseline pulse rate and blood pressure were recorded. An intravenous line was secured with an 18G cannula on the non-dominant hand and the parturient was preloaded with 500 ml of Ringer’s lactate solution.

Performing the Block: The parturient was placed in left lateral position. Under all aseptic precautions the L3-L4 interspace was chosen to perform the block. A skin wheal was raised in the midline over this space and the subcutaneous tissues were infiltrated with 1ml of 2% lignocaine using a 23G hypodermic needle. Combined spinal epidural technique performed with 18 G Weiss epidural needle and 27 G Whitaker pencil tip needle, by needle through needle technique. Epidural needle placed in the space by loss of resistance to air syringing technique in the midline. Spinal needle placed by needle through needle technique. 20 µg fentanyl deposited intrathecally after getting free flow of CSF through the spinal needle.

Test dose given with 3 ml of 2% xylocaine with adrenaline. After the confirmation of the epidural space, catheter placed with 3-4 cm in the space. 8 ml of 0.125% bupivacaine deposited through the catheter. The epidural technique performed with 18 G Touhey needle, loss of resistance to air syringing technique. Catheter placed 3-4 cm in the epidural space. Test dose of 3 ml of 2% lignocaine with adrenaline given. With the confirmation of catheter in epidural space, about 8 ml of 0.125% bupivacaine with 20 µg fentanyl given.

After the injection, the parturient was turned to her back and left uterine displacement was provided using a wedge under the right buttock.

Top ups of 5 ml of 0.125% bupivacaine was given as the patient experienced the painful uterine contractions and was given through the catheter in supine position with frequent aspiration and slowly. Mother’s vital parameters, progress of labour, efficacy of analgesia and foetal wellbeing were watched in co-ordination with the attending obstetrician. The operation theatre and personnel were kept ready for any possible eventualities arising out of complications or of surgical intervention.

OBSERVATIONS:
1. Mother’s vital parameters were recorded throughout the study, every 5 minutes for at least 15 min after the deposition of the drug and then every 15 min thereafter. Maternal hypotension was defined as a decrease in systolic B P of 20% of the basal or <100 mm Hg. Hypotension was planned to be treated with increased I.V fluid administration and/or vasopressor.
2. Time of onset of analgesia was noted. It was defined as the interval between the complete administration of the bolus dose of bupivacaine+fentanyl or intrathecal administration of fentanyl and appreciation of analgesia by the parturient. Peak analgesia was defined as the interval between the onset of analgesia to first lack of awareness of painful contraction.
3. Degree of pain relief—analgesia was measured using VAS (visual analogue scale) on 100 mm line.

4. Assessment of motor blockade—Motor blockade was assessed after the epidural block as per the modified Bromage scale. (0- No motor blockade, 1 - Unable to lift leg straight, 2 - Unable to flex knees, 3 - Unable to flex ankles.)

5. Top up doses: number of top up doses, duration between top ups were noted.

6. Assessment of progress of labour was done by attending obstetrician. Cervical dilatation, effacement, station of head, uterine contraction and FHR were recorded frequently.

7. Duration of individual stages of labour was noted.

8. Foetal monitoring—with electronic foetal monitor and auscultation of FHS every 15 min to know the type of deceleration if any.

9. Mode of delivery—spontaneous vaginal or instrumental or operative delivery and induction for the same were noted.

10. APGAR score was assessed at 1 and 5 minutes following delivery.

11. Complications/side-effects, if any like pruritus, urinary retention, accidental dural puncture, PDPH etc. were noted.

**STATISTICAL METHODS:** Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. The following assumptions on data are made: 1. Dependent variables should be normally distributed, 2. Samples drawn from the population should be random, and Cases of the samples should be independent. Student t test (two tailed, independent) has been used to find the significance of study parameters on continuous scale between two groups Inter group analysis) on metric parameters. Leven1s test for homogeneity of variance has been performed to assess the homogeneity of variance. Chi-square/Fisher Exact test has been used to find the significance of study parameters on categorical scale between two or more groups.

**Significant figures:**
- * Suggestive significance (P value: 0.05<P<0.10)
- ** Moderately significant (P value: 0.01<P ≤ 0.05)
- *** Strongly significant (P value: P≤0.01)**
**Statistical Software:** The Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver.2.11.1 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

**RESULTS:** A comparative two group study with 30 patients in Combined Epidural analgesia and 30 patients in Epidural analgesia is undertaken to study the to assess the efficacy of 0.125% bupivacaine with 20 µg fentanyl in relieving parturition pain and to compare the effectiveness of both techniques on the progress of labor, maternal satisfaction, mode of delivery, complications and neonatal outcome.

The two groups were similar with respect to age distribution, height, weight, BMI of the parturients (table 1 & 2).

The onset of analgesia was 1.98±0.33 min in group CSE and 5.00±1.64 min in group E (table 3). Peak action of analgesia was 4.15±0.41 min in CSE group and 9.87±1.97 min in group E. The onset and peak of analgesia was faster in group CSE and is statistically significant with p<0.001 (table 4). VAS score was statistically similar in both groups (table 5).

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The variations in blood pressure noted in SBP in 1st and 2nd stage were not statistically significant in both the groups (table 8). The variations noted in DBP were statistically significant in both groups. Parturients in group CSE had a basal DBP of 76mmhg which dropped to 73mmhg in first stage and 72mmhg in 2nd stage. In epidural group basal DBP was 78mmhg which dropped to 76.6mmhg in the 1st stage. In 3rd stage mean DBP was 78mmhg which was similar to the basal DBP. The basal DBP was significantly less in 2nd stage in CSE group compared to group E with respect to basal levels. This is statistically significant with p =0.001 (table 9).

Mean cervical dilatation in group CSE was 3.93±0.58 cm and 3.86±0.57cm in group E which was statistically similar in both the groups (table 10).

Mean duration of labor were not statistically significant for 1st and 2nd stages in the two groups. Duration of third stage was more in epidural group compared with CSE group and this was statistically significant (table 11).

63.3% of parturients in both the groups required only 1-2 top ups which was given on demand or when patient perceived pain. No top up was given in 16.7% and 10% parturients in group CSE and E respectively. Maximum top ups given was 5-6 for three parturients in CSE group and none in other group. Mean top up needed in CSE group was 1.70±1.46 and 1.67±0.99 in group E which was statistically insignificant (table 12).

Mean interval between the time of analgesia and the time of delivery is 3.53±1.62 hrs. in group CSE and 3.48±1.18 hrs. in group E showing no statistical significance (table 13).

Majority of the parturients in both the groups delivered vaginally without any instrumentation i.e. 80.0% in group CSE and 76.7% in group E. However, 16.7% parturients in group
E were delivered by LSCS compared to 6.7% in group CSE but the difference being not statistically significant with p=0.302 (table 14).

All neonates in group CSE and group E had APGAR scores between 7-8 at birth. However, all the neonates in both the groups had a score of 8-9 at 5 minutes. The difference between the groups was not statistically significant (p>0.05) concluding all neonates had good Apgar (table 15).

No complications or side effects were observed in the majority of parturients in group E. 46.7% of parturients in CSE group had pruritus compared to 6.7% in group E which subsided spontaneously. This difference was statistically significant (p<0.05). Three parturients in group E and one parturient in group CSE experienced urinary retention (table 16).

### Table 1: Age distribution of patients studied

<table>
<thead>
<tr>
<th>Age in years</th>
<th>Group CSE</th>
<th>Group E</th>
</tr>
</thead>
<tbody>
<tr>
<td>18-20</td>
<td>6 (20.0%)</td>
<td>4 (13.3%)</td>
</tr>
<tr>
<td>21-25</td>
<td>20 (66.7%)</td>
<td>20 (66.7%)</td>
</tr>
<tr>
<td>26-30</td>
<td>4 (13.3%)</td>
<td>6 (20.0%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>30 (100.0%)</td>
<td>30 (100.0%)</td>
</tr>
<tr>
<td><strong>Mean ± SD</strong></td>
<td>22.87±2.87 (18-30)</td>
<td>23.07±2.53 (18-28)</td>
</tr>
</tbody>
</table>

Samples are age matched with P = 0.776

### Table 2: Comparison of height, weight & BMI in two groups of patients studied

<table>
<thead>
<tr>
<th>Height, weight &amp; BMI</th>
<th>Group CSE</th>
<th>Group E</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height (cm)</td>
<td>159.00±3.53 (154-165)</td>
<td>159.87±3.15 (152-165)</td>
<td>0.321</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>60.77±3.16 (53-65)</td>
<td>60.93±3.30 (55-68)</td>
<td>0.843</td>
</tr>
<tr>
<td>BMI kg/m2</td>
<td>24.04±1.16 (21.19-27.06)</td>
<td>23.83±0.84 (21.76-25.54)</td>
<td>0.423</td>
</tr>
</tbody>
</table>

Samples are Height, Weight and BMI matched with P>0.05

### Table 3: Distribution of onset of analgesia in two groups of patients studied

<table>
<thead>
<tr>
<th>Onset of analgesia (min)</th>
<th>Group CSE</th>
<th>Group E</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>24 (80.0%)</td>
<td>0 (0.0%)</td>
</tr>
<tr>
<td>2-4</td>
<td>6 (20.0%)</td>
<td>14 (46.7%)</td>
</tr>
<tr>
<td>&gt;4</td>
<td>0 (0.0%)</td>
<td>16 (53.3%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>30 (100.0%)</td>
<td>30 (100.0%)</td>
</tr>
<tr>
<td><strong>Mean ± SD</strong></td>
<td>1.98±0.33 (1.50-2.50)</td>
<td>5.00±1.64 (3.00-10.00)</td>
</tr>
</tbody>
</table>

Onset of analgesia is significantly early in Group CSE (1.98min) compared to Group E (5.0min) with P = <0.001**
Mean Peak is significantly early in Group CSE compared to Group E with P = <0.001**

Distribution of VAS score statistically similar in two groups with P=1.000

Mean PR is significantly different in Group CSE compared to Group E with P = 0.001**
Mean SBP

<table>
<thead>
<tr>
<th>Group CSE</th>
<th>Group E</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal SBP</td>
<td>118.47±6.7 (110-130)</td>
<td>118.4±8.7 (103-134)</td>
</tr>
<tr>
<td>1st stage</td>
<td>114.9±7.36 (100-130)</td>
<td>112.13±7.43 (100-126)</td>
</tr>
<tr>
<td>2nd stage</td>
<td>115.07±9.68 (100-130)</td>
<td>112.07±7.46 (102-126)</td>
</tr>
</tbody>
</table>

Table 8: Comparison of Mean SBP in two groups of patients studied

Mean DBP

<table>
<thead>
<tr>
<th>Group CSE</th>
<th>Group E</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal DBP</td>
<td>76±6.37 (60-86)</td>
<td>78.13±5.17 (68-88)</td>
</tr>
<tr>
<td>1st stage</td>
<td>73.79±6.42 (64-90)</td>
<td>76.6±6.15 (62-86)</td>
</tr>
<tr>
<td>2nd stage</td>
<td>72.03±7.76 (60.0-92.0)</td>
<td>78.00±5.98 (66-90.0)</td>
</tr>
</tbody>
</table>

Table 9: Comparison of Mean DBP in two groups of patients studied

Cervical dilation(cm)

<table>
<thead>
<tr>
<th>No</th>
<th>%</th>
<th>No</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.00</td>
<td>6</td>
<td>20.0</td>
<td>7</td>
</tr>
<tr>
<td>4.00</td>
<td>20</td>
<td>66.7</td>
<td>20</td>
</tr>
<tr>
<td>5.00</td>
<td>4</td>
<td>13.3</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
<td>30</td>
</tr>
</tbody>
</table>

Mean ± SD

<table>
<thead>
<tr>
<th>Group CSE</th>
<th>Group E</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.93±0.58 (3.00-5.00)</td>
<td>3.86±0.57 (3.00-5.00)</td>
</tr>
</tbody>
</table>

Table 10: Distribution of Cervical dilation in two groups of patients studied

Mean cervical dilation is statistically similar in two groups with P = 0.656

Duration

<table>
<thead>
<tr>
<th>Duration</th>
<th>Group CSE</th>
<th>Group E</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st stage (hrs.)</td>
<td>5.18±1.79 (3-10)</td>
<td>5.78±2.27 (3-11)</td>
<td>0.266</td>
</tr>
<tr>
<td>2nd stage (min)</td>
<td>18.15±6.66 (10-37)</td>
<td>16.72±4.81 (10-30)</td>
<td>0.383</td>
</tr>
<tr>
<td>3rd stage(min)</td>
<td>5.17±0.91 (5-10)</td>
<td>6.33±2.60 (5-15)</td>
<td>0.024*</td>
</tr>
</tbody>
</table>

Table 11: Comparison of duration of labor in two groups of patients studied
Table 12: Distribution of number of tops ups in two groups of patients studied

<table>
<thead>
<tr>
<th>Tops ups</th>
<th>Group CSE</th>
<th></th>
<th>Group E</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Nil</td>
<td>5</td>
<td>16.7</td>
<td>3</td>
<td>10.0</td>
</tr>
<tr>
<td>1-2</td>
<td>19</td>
<td>63.3</td>
<td>19</td>
<td>63.3</td>
</tr>
<tr>
<td>3-4</td>
<td>3</td>
<td>10.0</td>
<td>8</td>
<td>26.7</td>
</tr>
<tr>
<td>5-6</td>
<td>3</td>
<td>10.0</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Mean ± SD
1.70±1.46 (0.00-5.00)
1.67±0.99 (0.00-3.00)

Distribution of no of tops ups is statistically similar in two groups with P = 0.918

Table 13: Distribution of Interval between analgesia and Time of Delivery (TOD) in two groups of patients studied

<table>
<thead>
<tr>
<th>Interval between analgesia and TOD</th>
<th>Group CSE</th>
<th></th>
<th>Group E</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>1-2</td>
<td>1</td>
<td>3.3</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>2-4</td>
<td>19</td>
<td>63.3</td>
<td>16</td>
<td>53.3</td>
</tr>
<tr>
<td>4-6</td>
<td>7</td>
<td>23.3</td>
<td>12</td>
<td>40.0</td>
</tr>
<tr>
<td>&gt;6</td>
<td>3</td>
<td>10.0</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Mean ± SD
3.53±1.62 (1.50-8.00)
3.48±1.18 (1.75-6.00)

Mean Interval between anal and TOD is statistically similar in two groups with P = 0.899

Table 14: Distribution of mode of delivery in two groups of patients studied

<table>
<thead>
<tr>
<th>Mode of delivery</th>
<th>Group CSE</th>
<th></th>
<th>Group E</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Normal</td>
<td>24</td>
<td>80.0</td>
<td>23</td>
<td>76.7</td>
</tr>
<tr>
<td>Instrumental</td>
<td>4</td>
<td>13.3</td>
<td>2</td>
<td>6.7</td>
</tr>
<tr>
<td>LSCS</td>
<td>2</td>
<td>6.7</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>100.0</td>
<td>30</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Distribution of mode of delivery is statistically similar in two groups with P=0.302

Table 15: Distribution of Apgar score at 1 minute in two groups of patients studied

<table>
<thead>
<tr>
<th>Apgar score</th>
<th>Group CSE (n=30)</th>
<th></th>
<th>Group E (n=30)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>At 1 minute</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;6</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>7-8</td>
<td>30</td>
<td>100.0</td>
<td>30</td>
<td>100.0</td>
</tr>
<tr>
<td>&gt;9</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
At 5 minutes

<table>
<thead>
<tr>
<th></th>
<th>Group CSE (n=30)</th>
<th>Group E (n=30)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>%</td>
</tr>
<tr>
<td>Nil</td>
<td>15</td>
<td>50.0</td>
</tr>
<tr>
<td>Present</td>
<td>15</td>
<td>50.0</td>
</tr>
<tr>
<td>• Pruritus</td>
<td>14</td>
<td>46.7</td>
</tr>
<tr>
<td>• Urinary retention</td>
<td>1</td>
<td>3.3</td>
</tr>
<tr>
<td>• Hypotension</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>• Nausea/Vomiting</td>
<td>0</td>
<td>0.0</td>
</tr>
</tbody>
</table>

Table 15: The neonatal outcome as assessed by APGAR score in two groups of patients studied

Table 16: Distribution of complications in two groups of patients studied

Incidence of complications are significantly more in Group CSE (50.0%) when compared to only 16.7% in Group E with p=0.006**

DISCUSSION: The ideal labour analgesic technique should be effective, safe for mother and foetus, should be easy to administer, should provide consistent, predictable and rapid onset of analgesia in all stages of labour, should be devoid of motor blockade and should preserve the stimulus for expulsive efforts during the second stage of labour.

Lumbar epidural technique as a means of obstetric pain relief has established its supremacy. Epidural analgesia is used principally for pain relief during labour. It is estimated that some 20% of all the parturients now receive epidural analgesia for pain relief in labour. Safe and effective relief of pain during labour and delivery accomplished by the skill full use of epidural analgesia prevents the stress response in the mother. Maternal hypoxemia, hypocapnia, catecholamine secretion leading to uterine hypoperfusion, foetal hypoxia and acidosis are avoided. Obstetricians and Anaesthesiologists have always feared that incidence of instrumental deliveries in women receiving epidural analgesia could be higher than in those who do not receive it.

Factors contributing to instrumental delivery are:
1. Diminished Fergusson’s reflex due to diminished pain and sensation of uterine contraction and diminished perception of the need to bear down at full cervical dilatation.
2. Motor blockade leading to reduced propulsive efforts.
3. Inadequate rotation of the presenting part due to weakened pelvic floor musculature.

Studies have revealed that the threshold of the obstetricians to perform assisted delivery is definitely lower when epidural analgesia is already present. Bupivacaine still remains the most often used local anaesthetic. Various workers have used varying concentrations of bupivacaine. Undiluted bupivacaine (0.5%) was popular for initiation and maintenance of labour analgesia. However it caused dense motor blockade and interference with maternal awareness of contractions.
providing excellent pain relief in labour, epidural analgesia using local anaesthetics alone produces motor block in 85% of the patients and associated with a prolonged second stage and an increased incidence of instrumental delivery\textsuperscript{7}. In an attempt to reduce these undesirable effects, efforts were made to reduce the concentration and total dose of local anaesthetics used. Adjuvants like fentanyl were added so as to decrease the bupivacaine concentration to as low as 0.0625%. With all the efforts factors that have generated intense interest in epidural analgesia are:

1. Decreasing the local anaesthetic concentration
2. Combining with opioids.
3. Combined spinal epidural technique.

Bupivacaine in the concentration of 0.125% were used by Bleyert\textsuperscript{68}, Kahn et al\textsuperscript{8,9} Guisasola.\textsuperscript{10} They observed there was significant avoidance of motor blockade. There was no prolongation of second stage of labour and no difference in the mode of delivery. Li et al studied the efficacy of bupivacaine by reducing the concentration from 0.25% upto 0.0625% as bolus.\textsuperscript{11} Purdy et al compared 0.5%, 0.375%, 0.25% bupivacaine given as bolus.\textsuperscript{12} They observed that by reducing the concentration, quality of analgesia did not differ. However lower concentration of local anaesthetics minimised or prevented the motor block. However the use of low concentrations of bupivacaine provides suboptimal, short lived analgesia when used alone.\textsuperscript{13}

Epidural opioids offer the possibility of analgesia without motor block, but when used alone do not provide satisfactory analgesia throughout labour.\textsuperscript{7} Addition of an opioid to local anaesthetic can provide effective analgesia with bupivacaine sparing and reduction in motor block.\textsuperscript{7} Fentanyl has been the mainstay of epidural analgesia. Recently alfentanil and sufentanil have been tried for labour analgesia without added advantage.\textsuperscript{14} Another development is combined spinal epidural technique; where in 15-25µg fentanyl ± 1.5 -2.5mg of bupivacaine is injected into subarachnoid space followed by epidural analgesia, provided effective and faster onset of analgesia and flexibility of using epidural catheter.

In the context of above mentioned developments we have undertaken a study to compare epidural analgesia with CSE for labour.

**Commencing of Epidural Analgesia:**

Commencing of epidural analgesia in early labour can cause:

1. Slowing or arrest of labour necessitating the use of oxytocin.
2. Motor paralysis of pelvic and abdominal muscles resulting in lack of internal rotation and insufficient bearing down force.
3. Absence of Fergusson’s reflex.
4. Increased risk of hypotension.
5. Accumulation of local anaesthetics in maternal and foetal blood.
6. Unpleasant subjective awareness of numbness and paralysis in mother.\textsuperscript{8}

Most workers have commenced epidural analgesia when cervical dilatation was 3 cm or more. Since the active phase of first stage of labour is between 4cm till full cervical dilatation, in our study the labour analgesia was instituted with cervical dilatation between 3-5 cm, in view of making the technique convenient and comfortable for both patient and anaesthetist and avoid risk of injection of the drug at the time of painful uterine contractions.
**Technique:** Stoddart et al preloaded the parturients with 1000ml of compounded ringer’s lactate solution. David H Chestnut et al gave an I V infusion of 750ml of ringer lactate over 10-15 min before administering epidural analgesia. No preloading was done by James et al, but a patient I.V line was maintained before proceeding with the study. In our study, preloading was done with 500ml of ringer’s lactate solution before starting the block.

**Test Dose:** The ideal test dose should differentiate between the correct placement of the catheter and an intravascular or intrathecal placement or injection. Stoddart et al used 3ml of 0.5% bupivacaine as test dose followed 5 min later with 5ml of 0.5% bupivacaine. After analgesia was established they proceeded with the study solution (0.125% bupivacaine with 1 µg/ml fentanyl or 0.0625% bupivacaine with 1µg/ml fentanyl) as continuous infusion. Cohen S E used a test dose of 3ml of 1% lignocaine with 1:200000 epinephrine after which bupivacaine in concentrations of 0.25% to 0.0625% with fentanyl in various concentrations were given. David Chestnut et al used 3 ml of 1.5% lignocaine with 1:200000 epinephrine followed 5 min later by 6 ml of 0.125% bupivacaine with 0.0008% fentanyl and at 10 min by continuous infusion of 0.0625% bupivacaine + fentanyl.

Alternate test dose:
1. Isoproterenol.
2. Injection of air into epidural veins.
3. Fentanyl-subjective symptoms of light headedness as a marker of IV versus epidural injection.

However none are very reliable. After CSE, many anaesthesiologists elect to initiate an epidural injection immediately. The value of a test dose in the setting has not been established. It is believed that every dose that is injected is a test dose that should be given slowly in fractional doses. In our study we used a test dose of 2% lignocaine with 1:200000 epinephrine of 3 ml. After 5 min of test dose, bupivacaine 0.125% solution 8ml with/without fentanyl 20 µg was given.

**Catheter Placement and Drug Administration:** In a study by Lyon the epidural catheter was placed in L2-L3 or L3-L4 interspace in the sitting position and catheter was threaded in cephalad direction with 3-4 cm inside the epidural space. Stoddart et al also used the same method. Buggy et al used L2-L3 inter space and the procedure performed in left lateral position with epidural catheter placed in cephalad direction with 3-4 cm inside the epidural space. Purdy et al in their study observed less sacral blockade and rectal discomfort when the catheter was threaded cephalad. In our study the procedure was performed in left lateral position, in L3-L4 interspace and the catheter was threaded in cephalad direction with 3-4 cm inside the epidural space. Top ups were given in supine position with 5 ml 0.125% bupivacaine in both the groups.

**PAIN RELIEF:**

**Onset of Analgesia:** CSE technique has the advantage of rapid onset of profound analgesia. Maternal satisfaction is high. It has been observed that subsequent analgesia can be achieved with lower doses of local anaesthetics if prior intrathecal opioid had been used. In our study the onset of analgesia and peak of analgesia is faster in CSE group of mean 1.98 min and 4.15 min respectively when compared to 5 min and 9.87 min of group E respectively. This is statistically significant with p<0.001 for both onset and peak of analgesia in favour of CSE. There is no much difference in quality of analgesia as
assessed by VAS between the two groups. There is no difference in number of top ups and mean interval between onset of analgesia and time of delivery i.e., there is no difference in mean duration of analgesia between the two groups.

**Motor Block:** David H Chestnut H K et al reported that 2 patients out of 37 had a detectable motor block when using 0.125% bupivacaine with 0.0002% fentanyl infusion. James et al reported that 39 patients out of 40 patients retained motor power judged by the ability to walk and 60% were able to get out of bed during labour. Buggy et al used 0.1% bupivacaine and 0.0002 % fentanyl in their study and reported posterior column impairment. They recommended that the parturients be made only to sit or stand up vertically and the parturients were not allowed to ambulate. The efficacy of the block is related to spread of the drug and the number of the dermatomes blocked. Owen et al used 0.125% bupivacaine infusion and found mild motor block (0 & 1 modified bromage scale). In our study motor blockade was assessed using modified bromage scale. No motor block was observed in any parturient in either group. This concurs with the studies of Cohen et al.

**Hemodynamic Effects:** In our study there were no significant changes in mean pulse rate in both the groups. The main cause of hemodynamic disturbances during neuraxial blockade in labour analgesia is widespread vasomotor blockade, which is aggravated by supine hypotension syndrome. The former can be minimised by using lower volume and concentrations of local anaesthetics directed at the desired spinal segments. The supine hypotension syndrome can be prevented by tilting the parturient to the left side, with a wedge or a pillow and ensuring that they remain on that side. Any hypotension despite the above precautions should be treated with rapid fluid infusion and/or administration of vasopressor, augmented lateral tilt and oxygen by mask. In our study there was a slight fall in systolic blood pressure in first and second stages of labour in both the groups but statistically insignificant. The diastolic blood pressure decreased slightly in both the groups in both the stages of labour but the decrease in DBP in 2nd stage was to a mean value of 72.03 from basal of 76 mm of Hg in group CSE and to 78 from basal of 78.13 mm of Hg in group E. The drop in DBP in group CSE in 2nd stage is statistically significant with p<0.001.

**Duration of Labour:** Sheila E Cohen et al reported a shortened first stage in women who received bolus injection of bupivacaine (22.5 mg) and fentanyl 50 or 100 µg compared with bupivacaine alone (22 mg) or bupivacaine (7.5 mg) and fentanyl 100 µg. They speculated that the former patients may have reduced catecholamine release as a consequence of better pain relief and anxiety. Reynolds et al also reported the combination of bupivacaine 10-12 mg with fentanyl 80 µg to effectively relieve first stage pain rather than bupivacaine or fentanyl used alone, thus shortening the first stage. Pain and high level anxiety during labour can lead to a surge in endogenous catecholamines, in turn initiating a vicious cycle of in coordinate uterine action and prolonged labour. Epidural analgesia by annulling pain would be expected to correct this. On the other hand deeper than the judicious analgesia could cause motor paresis leading to arrested labour. It is also to be impressed on the motor that little pain relief rather than no pain holds the key to success. In view of afore mentioned idea bupivacaine 0.125% solution was made use of in our study. In this study the difference in mean duration were not statistically significant for 1st and 2nd stages in the two groups. Duration of third stage was more in epidural group compared with CSE group and this was statistically significant.
Mode of Delivery: A study by Michael concluded that the epidural analgesia given before active stage of labour more than doubled the probability of undergoing caesarean section. If given in the active phase of labour, epidural analgesia does not increase the rates of caesarean section.25 A study by Wong C A et al revealed that neuraxial analgesia in early labour did not increase the rate of caesarean delivery and it provided better analgesia and resulted in shortened duration of labour than systemic analgesia.29 Ohel G et al concluded that initiation of epidural analgesia in early labour following the first request for epidural, did not result in increased caesarean deliveries, instrumental vaginal deliveries and other adverse effects and it was associated with shortened first stage of labour and was clearly preferred by women30. In our study the mode of delivery was spontaneous vaginal delivery in most of the parturients of about 80% in CSE and 76.7% in group E. Instrumental delivery of 13.3% and 6.7% in CSE and epidural respectively. Caesarean sections of 6.7% and 16.7% in CSE and epidural respectively. There was no statistically significant difference between the two groups regarding the mode of delivery.

Neonatal Outcome: The mean APGAR score in both groups in the present study was 8 at 1 minute and 9 at 5 minutes without statistical significance. Owen et al found APGAR scores to be >7 by 5 minutes in all neonates. Bleyaert et al found that 91% of neonates at 1 minute and 99% of neonates at 5 minutes had scores of more than 7 while using bupivacaine alone. According to N. Rawal M.D et al Apgar score and neurobehavioral evaluation did not show any differences between the two groups of neonates.

Side Effects: In the present study, 50% of the parturients in group CSE and 83% in epidural group did not experience any side effects. 46.7% parturients in group CSE had pruritus and only 6.7% had in epidural group had pruritus which was statistically significant. Studies by Cohen et al (26-32%) and Chestnut et al (7-12%) have observed a higher incidence of pruritus. According to Mark C. Norris et al Women who received CSE analgesia were more likely to itch (41.4% vs. 1.3%) compared to epidural group. Fewer than 10% developed hypotension with either technique.

CONCLUSION: We conclude that, the analgesia provided during labor by both the techniques was satisfactory and comparable. The onset and peak of analgesia was faster in CSE than epidural analgesia. The quality and duration of analgesia were comparable in both the groups. The drop in DBP in 2nd stage of labor in group CSE was significant. The duration of 3rd stage of labor in group CSE was significantly shortened. The incidence of pruritus is more in CSE than epidural technique.

There is no motor blockade in both the groups and comparable. Fetal outcome is comparable in both the groups. In conclusion the onset and peak of analgesia is faster in CSE than epidural technique but is associated with higher incidence of pruritus. The quality, duration of analgesia, motor blockade and fetal outcome are all comparable in both the groups.

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