A COMPARATIVE STUDY OF BUPIVACAINE AND FENTANYL V/s BUPIVACAINE AND BUTORPHANOL IN LABOUR ANALGESIA BY EPIDURAL TECHNIQUE
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ABSTRACT: BACKGROUND: Pain is a subjective experience with sensory and emotional components that are inextricably linked to each other. Pain during labour is very intense for many mothers. Severe labour pains may adversely affect both mother and fetus. Variety of regional analgesia techniques are available, Of all these techniques epidural analgesia using local anaesthetics and opiates has gained popularity as a safe and effective technique of pain relief largely replacing other modalities. AIM: The present study was undertaken to compare bupivacaine and fentanyl with a combination of bupivacaine and butorphanol by intermittent bolus epidural technique in relieving pain during labour. DESIGN: Randomized control study. METHODS: A total number of 100 parturients studied were divided into two groups randomly. Group-1: received a combination of Bupivacaine and Fentanyl. The initial bolus dose was 0.1% Bupivacaine 10ml with 2mcg/ml [20mcg] of Fentanyl and top up doses were 0.1% Bupivacaine with Fentanyl 2mcg/ml [10ml]. Group-2: This Group received a combination of Bupivacaine and Butorphanol. The initial bolus dose was 0.1% Bupivacaine 10ml with 0.01% of Butorphanol [1mg] and top up doses were with 0.1% Bupivacaine [10ml]. Maternal blood pressure, pulse rate, fetal heart rate were monitored every 1-2 min for first 10 min and then every 5-10 min for subsequent 30 min and later every half an hour. Time of onset of analgesia, level of sensory blockade and motor blockade, if any was noted. VISUAL ANALOGUE PAIN SCALE [VAPS] assessed pain at different time intervals. The sedation was assessed by WILSON GRADING, BROMAGE SCALE assessed the motor blockade. RESULTS: The onsets of analgesia were quicker in group-1 parturients who received 0.1% bupivacaine with 0.0002% fentanyl. The duration of analgesia with the 1st dose was significantly more in the group-2 also the requirement of top up doses was also less in group-2 and also the quality in group-2 was superior. There was no significant increase in the requirement of instrumentation, surgical intervention in both the groups. Neonatal outcome was good and almost equal in both the groups without any respiratory depression even with addition of low dose butorphanol by epidural route. CONCLUSION: From this study it may be concluded that using a combination of 0.1% Bupivacaine with 1mg Butorphanol during epidural analgesia for labour provides excellent pain relief, prolonged duration of action with simultaneously decreasing the top-ups required, thereby reducing the total local anesthetic requirement compared to 0.1% bupivacaine with 0.0002% fentanyl [20mcg]

KEYWORDS: Bupivacaine, Butorphanol, Epidural Analgesia, Fentanyl, Labour Analgesia.

INTRODUCTION: International association for the study of pain in 1979 defines pain as "An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage".
Pain is a subjective experience with sensory and emotional components that are inextricably linked to each other.

The perception of pain and response to it vary from one parturient to another, from time to time and from place to place. This variability of response is nowhere more marked than during labour. This pain during labour is very intense for many mothers. Duration of labour, induction of labour by oxytocics, psychological background, parity and economical status are the few factors that influence pain response during labour. At this highly emotional time a woman's perception of labour pain can be made worse by unsympathetic staff and surroundings and improved by sympathy, comfort, encouragement and distraction.

Severe labour pains may adversely affect both mother and fetus. Excessive maternal suffering causes increased mechanical work, marked maternal hyperventilation and increased release of catecholamines which is a physiological response to pain. These natural responses result in maternal hypoxia, hypocapnia leading to decreased uterine blood flow, uterine rhythmicity and contractility. Ultimately these can adversely affect fetus by fetal hypoxia and metabolic acidosis.

The effective pain relief can decrease this response and improve uterine blood flow thus restoring the uterine contractions to normal, though many mothers can tolerate the stress of labour without adverse neonatal outcome. Women with prolonged labour induced by oxytosics, and high risk pregnancies associated with maternal diseases have decreased maternal reserve and fetomaternal compromise. They will benefit from stable maternal physiology provided by complete pain relief. There have been many approaches to pain relief in labour throughout the history up to the present time such as systemic analgesics, both narcotics and non-narcotics, inhalation analgesics like nitrous oxide, trichloroethylene, methoxyflurane and regional techniques.

Variety of regional analgesia techniques are available to offer flexibility while relieving pain during labour including intrathecal opioids, epidural local anaesthetics alone epidural local anaesthetics and epidural opiates, caudal technique using local anaesthetics and opioids.

Of all these techniques epidural analgesia using local anaesthetics and opiates has gained popularity as a safe and effective technique of pain relief largely replacing other modalities. It is the only pharmacological technique capable of producing complete pain relief with opioids counteracting visceral pain and local anaesthetics controlling somatic pain effectively. But it is not without complications, so greater skill, experience and complete facilities for resuscitation make the technique a success.

The primary indication for epidural analgesia is labour pain. It is the only effective technique to relieve severe labour pain. It offers trial of labour in high risk parturients, previous caesarian section, anticipated difficult intubation and obesity.

Epidural analgesia has been shown by Jouppila et al; significantly, to improve intervillous blood flow in preeclamptic parturients. Ramos santos et al, using doppler techniques showed that in preeclamptics parturients epidural blockage decreases significantly the uterine vascular resistance.

Maternal indications of epidural analgesia are preeclampsia, pulmonary, renal and some cardiac problems. The fetal indications are prematurity and small for date babies, due to their excellent analgesia, increase the maternal oxygen saturation, and allow a more controlled delivery because of relaxed pelvic floor muscles and decreased urge to push. Also epidural analgesia decrease the risk of intracerebral bleeding in premature babies, improves acid base status and causes virtually no neonatal depression.

Many drugs find place in drug armamentarium in regional techniques of obstetric analgesia.
such as xylocaine, bupivacaine, tetracaine etc. Bupivacaine, an amide amino group of local anaesthetics scored as a better agent of choice in pain relief of labour.\(^4\) It produces excellent sensory blockade with less motor blockade when used in the concentrations of 0.0625% to 0.25%. It also has long duration of action with less tachyphylaxis. It is having low maternal ratio of 0.3 and minimal effects on neonatal neurobehaviour. These advantages made it a better agent of choice for epidural analgesia for labour.

Further many opioid analgesics are being used such as morphine, pethidine, fentanyl, sufentanil, tramadol, butorphanol.\(^5\) Fentanyl is a highly lipid-soluble, strong \(\mu\)-receptor agonist and phenyl piperidine derivative\(^6\) with a rapid onset and short duration of action like other opioids. Fentanyl also acts upon the opioid receptors located in areas of brain and spinal cord (Substantia gelatinosa). It has potency 76-125 times that of morphine. Butorphanol is a synthetic opioid analgesic, which is widely used for different types of pain relief. Butorphanol has been frequently used for post-operative analgesia and labor analgesia.\(^7,8\) Like other opioids, butorphanol also act upon the opioid receptors located, in areas of brain and spinal cord (Substantia gelatinosa). It has potency of 7 times that of morphine. When used in low doses in combination with local anaesthetic for labour the side effects and complications are very much reduced.\(^9\) Thus by extending the advantages and beneficial effects of both opioids and local anaesthetics, one can improve maternal satisfaction, duration of action and depth of block, simultaneously decreasing the dosage of each drug and also avoiding the adverse effects of these drugs.

Previous studies have compared the two narcotics for post-operative epidural analgesia.\(^10,11,12\)

The present study was undertaken to compare bupivacaine and fentanyl with a combination of bupivacaine and butorphanol by intermittent bolus epidural technique in relieving pain during labour.

**METHODS:** The present clinical study on 'Obstetric analgesia by epidural route' has been carried out at Government Govt. Maternity Hospital, Kakatiya Medical College Warangal. The study was undertaken to compare the effectiveness of Bupivacaine and Fentanyl v/s Bupivacaine and Butorphanol in relieving pain during labor.

A total number of 100 parturients studied were divided into two groups randomly. All of them were between age groups of 18-26 years and their deliveries were expected to be normal vaginal deliveries. Group -1 and Group-2 are study groups.

Hematological parameters including hemoglobin level, clotting time, bleeding time and Biochemical parameters like blood sugar, blood urea, serum creatinine were noted and were within the normal limits.

Neonatal evaluation was done in all the cases with APGAR score at 1 min and 5min intervals. This study has been approved by the hospital ethical committee.

**Inclusion Criteria:**
1. Healthy Gravida I patients at term (ASA I/II).
2. Materna request for epidural analgesia.
3. Well informed literate subjects.
4. Age group 18- 30 years.
5. Women in active labour with cervical dilatation in primi of 3-5 cms.
6. Vertex presentation.
Exclusion Criteria:
1. Patients unwilling for the procedure.
2. Parturients- multigravida.
3. Parturients with multiple pregnancies.
4. Severe anaemia.
5. Cephalo-pelvic disproportion.
7. Previous LSCS.
8. History of antepartum haemorrhage.
9. History of allergy to local anaesthetic.
11. Diabetes mellitus.
12. History of psychiatric or neurologic disease.
13. Pregnancy induced hypertension.

**Group-1:** This group of parturients received Bupivacaine with Fentanyl 0.0002% during the procedure until the delivery of fetus. The loading dose consisted of 10ml of Bupivacaine 0.1% and Fentanyl 0.0002% [20mcg]. The top up doses were 10ml of 0.1% Bupivacaine and Fentanyl 0.0002%, administered whenever the parturients complained of pain. When parturients enters into second stage a further 12-15ml was injected with parturients in sitting position or semi-sitting position.

**Group-2:** This group of parturients received Bupivacaine with Butorphanol 1mg. The loading dose consisted of 10ml of Bupivacaine 0.1% and 0.01% Butorphanol. The top up doses included Bupivacaine 0.1% alone in 10ml solution whenever the parturients complained of pain. When parturients enter into second stage, then an additional dose of 12-15ml was injected with parturients in sitting position or semi-sitting position. The stages and progress of labor was monitored with the help of an obstetrician.

**Timing of Induction of Epidural Analgesia:** Epidural analgesia for child birth is administered in two stages and depending upon the demand of the parturient. Identification of the stage of labor was done with the help of the obstetrician.

<table>
<thead>
<tr>
<th>Presenting part</th>
<th>Engaged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervical effacement</td>
<td>100%</td>
</tr>
<tr>
<td>Cervical dilatation</td>
<td>3-5cm for primigravida</td>
</tr>
<tr>
<td>Uterine contractions</td>
<td>Duration &gt;30 seconds</td>
</tr>
<tr>
<td></td>
<td>Interval: 3 uterine contractions/10 min</td>
</tr>
</tbody>
</table>

Assessment of Stage -1

Segmental sensory block T10 - L1 is required in relation to stretching of uterine tissues and simultaneously dilatation of cervix and stretching of lower segment.
**MONITORING:** Maternal blood pressure, pulse rate, fetal heart rate were monitored every 1-2 min for first 10 min and then every 5-10 min for subsequent 30 min and later every half an hour. Time of onset of analgesia, level of sensory blockade and motor blockade, if any was noted. VISUAL ANALOGUE PAIN SCALE [VAPS] assessed pain at different time intervals.

**Visual Analogue Pain Scale (VAPS):** Instruct the patient 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’.

**The Sedation was assessed by:**

**WILSON GRADING:**

<table>
<thead>
<tr>
<th>Sedation Level</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Awake, alert</td>
<td>1</td>
</tr>
<tr>
<td>Alert, drowsy</td>
<td>2</td>
</tr>
<tr>
<td>Sedation arousable by verbal commands</td>
<td>3</td>
</tr>
<tr>
<td>Sedation arousable by mild physical pain</td>
<td>4</td>
</tr>
<tr>
<td>Not arousable by pain</td>
<td>5</td>
</tr>
</tbody>
</table>
Progress of labor and site effects if any were noted in the epidural record sheet. During the procedure the supine position was avoided as far as possible. Care was taken to ensure that urinary bladder does not become over distended.

Administration through the intravenous cannula was continued throughout the procedure with either ringer lactate or normal saline depending on the blood pressure of the mother.

After delivery an additional dose of the respective drug was given before removal of the epidural catheter for further analgesia. Catheter was checked for any damage and ensured that no portion of the epidural catheter was retained. The puncture site at the skin was cleaned with antiseptic and covered with adhesive tape over a sterile gauze pieces.

All the newborns in both the groups were assessed for the effect of the drug by determining the APGAR scores immediately after delivery at 1min and 5min.

**OBSERVATIONS AND RESULTS:** The present clinical study consists of 100 parturients divided into [Group-1: n =50] [Group-2: n =50]. All parturients studied were primigravidae.

Group 1: 50
Group 2: 50

**STATISTICAL ANALYSIS:** In our study data was expressed as mean ± standard deviation where appropriate, statistical analysis for parametric data which included age, height, weight, cervical dilatation, onset of analgesia, duration of analgesia, number of top up doses. Probability values <0.005 were considered as statistically significant.

**AGE:** All parturients were between the ages of 18-26 years. (TABLE 1)

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>23.38</td>
<td>22.48</td>
</tr>
<tr>
<td>Median</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td>Mode</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>2.47345</td>
<td>2.20611</td>
</tr>
</tbody>
</table>

Unpaired student t test results

**P value and Statistical Significance:**

The two-tailed P value equals 0.0577

By conventional criteria, this difference is considered to be not quite statistically significant.
HEIGHT: (TABLE 2): All parturient were between heights of 150 - 160 cms Statistical analysis reveals the following data in cms.

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>160.07</td>
<td>160.18</td>
</tr>
<tr>
<td>Median</td>
<td>160.75</td>
<td>160</td>
</tr>
<tr>
<td>Mode</td>
<td>161</td>
<td>164</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>4.95182</td>
<td>4.82422</td>
</tr>
</tbody>
</table>

Table 2

Unpaired Student t test results

P value and Statistical Significance:
The two-tailed P value equals 0.9106
By conventional criteria, this difference is considered to be not statistically significant.

Intermediate Values used in Calculations:
\( t = 0.1125 \)
Standard error of difference = 0.978

WEIGHT: (TABLE 3)
All parturients were weighing between 55-65kgs. Statistical analysis reveals the following data in kgs.

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>60.48</td>
<td>60.02</td>
</tr>
<tr>
<td>Median</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>Mode</td>
<td>63</td>
<td>58</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>2.48251</td>
<td>2.02777</td>
</tr>
</tbody>
</table>

Table 3

Unpaired t test results

P value and Statistical Significance:
The two-tailed P value equals 0.3127
By conventional criteria, this difference is considered to be not statistically significant.

Intermediate Values used in Calculations:
\( t = 1.0147, \) Standard error of difference = 0.453

INITIATION OF EPIDURAL ANALGESIA (TABLE 4)
The epidural analgesia was initiated to parturients with cervical dilatation as depicted below:

<table>
<thead>
<tr>
<th></th>
<th>3cm</th>
<th>4cm</th>
<th>5cm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group-1</td>
<td>43[86%]</td>
<td>5[10%]</td>
<td>2[4%]</td>
</tr>
<tr>
<td>Group-2</td>
<td>42[84%]</td>
<td>6[12%]</td>
<td>2[4%]</td>
</tr>
</tbody>
</table>
Table 4

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Parameter</th>
<th>Group 1</th>
<th>Group 2</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Primigravida</td>
<td>50(100%)</td>
<td>50(100%)</td>
<td>-</td>
</tr>
<tr>
<td>2</td>
<td>Age(years)</td>
<td>23.38 ± 2.47</td>
<td>22.48 ± 2.20</td>
<td>Not significant</td>
</tr>
<tr>
<td>3</td>
<td>Height(cms)</td>
<td>160.07 ± 4.95</td>
<td>160.18 ± 4.82</td>
<td>Not significant</td>
</tr>
<tr>
<td>4</td>
<td>Weight(kgs)</td>
<td>60.48 ± 2.48</td>
<td>60.02 ± 2.02</td>
<td>Not significant</td>
</tr>
<tr>
<td>5</td>
<td>Cervical dilatation(cms)</td>
<td>3.06 ± 0.37</td>
<td>3.08 ± 0.39</td>
<td>Not significant</td>
</tr>
<tr>
<td>6</td>
<td>Oxytocics used</td>
<td>35(70%)</td>
<td>36(72%)</td>
<td>Not significant</td>
</tr>
</tbody>
</table>

Table 5

No differences were noted in demographic characteristics of each group.

Comparison of Onset of Analgesia: (TABLE 6)

The onset of analgesia was taken as the time from injection of the drug and the time at which parturient appreciated pain relief (in minutes).

Table 6

<table>
<thead>
<tr>
<th>Sl. No.</th>
<th>Parameter</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mean</td>
<td>8.18</td>
<td>12.68</td>
</tr>
<tr>
<td>2</td>
<td>Median</td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td>3</td>
<td>Mode</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>4</td>
<td>Standard deviation</td>
<td>1.68656</td>
<td>0.95704</td>
</tr>
</tbody>
</table>

P value and Statistical Significance:

The two-tailed P value is less than 0.0001.

By conventional criteria, this difference is considered to be extremely statistically significant.
Confidence Interval:
The mean of Group One minus Group Two equals -4.5000000.
95% confidence interval of this difference: From -5.0442227 to -3.9557773.

Intermediate Values used in Calculations:
t = 16.4089.
Standard error of difference = 0.274.
It indicates that the onset of analgesia is faster in group-1 parturients compared to group-2 parturients.

Comparison of Duration of Analgesia with First Dose: (Table 7): The duration of analgesia with the first (loading) dose was taken as a time for complete pain relief to the time when the parturients first complained of pain (in minutes).

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>68.68</td>
<td>92.16</td>
</tr>
<tr>
<td>Median</td>
<td>68.5</td>
<td>90.5</td>
</tr>
<tr>
<td>Mode</td>
<td>75</td>
<td>76.109</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>9.19059</td>
<td>14.24188</td>
</tr>
</tbody>
</table>

Table 7

Unpaired t test results

P value and Statistical Significance:
The two-tailed P value is less than 0.0001
By conventional criteria, this difference is considered to be extremely statistically significant.

Confidence Interval:
The mean of Group One minus Group Two equals -23.4800000
95% confidence interval of this difference: From -28.2369155 to -18.7230845

Intermediate Values used in Calculations:
t = 9.7953
Standard error of difference = 2.397
It indicates that duration of analgesia is more in group-2 parturients compared to group-1 parturients.

Comparison of Total Number of Doses Required (Table 8): The statistical analysis of total number of doses required by parturients in the study group is as follows:

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>4.58</td>
<td>2.82</td>
</tr>
<tr>
<td>Median</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Mode</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>0.7848</td>
<td>0.71969</td>
</tr>
</tbody>
</table>

Table 8

Unpaired t test results
P value and Statistical Significance:
The two-tailed P value is less than 0.0001.
By conventional criteria, this difference is considered to be extremely statistically significant.

Confidence Interval:
The mean of Group One minus Group Two equals 1.7600000.
95% confidence interval of this difference: From 1.4611593 to 2.0588407.

Intermediate Values used in Calculations:
t = 11.6874
Standard error of difference = 0.151.
It indicates the group-1 parturients required more number of doses than group-2 parturients.

COMPARISON OF DURATION OF LABOUR (TABLE 9): The duration of labour was calculated from the initiation of epidural analgesia to the time of delivery of fetus in minutes.

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>302.9</td>
<td>290.18</td>
</tr>
<tr>
<td>Median</td>
<td>309</td>
<td>292.5</td>
</tr>
<tr>
<td>Mode</td>
<td>310</td>
<td>321</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>42.92673</td>
<td>47.49423</td>
</tr>
</tbody>
</table>

Table 9

Unpaired t test results.

P value and Statistical Significance:
The two-tailed P value equals 0.1632.
By conventional criteria, this difference is considered to be not statistically significant.

Confidence Interval:
The mean of Group One minus Group Two equals 12.7200000.
95% confidence interval of this difference: From -5.2466274 to 30.6866274.

Intermediate Values used in Calculations:
t = 1.4050.
Standard error of difference = 9.054.

COMPARISON OF APGAR SCORES (TABLE 10): The neonatal outcome was assessed by APGAR scoring system at 1 min and 5 min.
The Comparison Statistical Data is tabulated as Follows:

<table>
<thead>
<tr>
<th></th>
<th>APGAR 1 minutes</th>
<th>APGAR 5 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>GROUP</td>
<td>MEAN</td>
<td>MEDIAN</td>
</tr>
<tr>
<td>Group-1</td>
<td>7.36</td>
<td>8</td>
</tr>
<tr>
<td>Group-2</td>
<td>7.6</td>
<td>8</td>
</tr>
<tr>
<td>Group-1</td>
<td>9.36</td>
<td>10</td>
</tr>
<tr>
<td>Group-2</td>
<td>9.6</td>
<td>10</td>
</tr>
</tbody>
</table>

Table 10

Unpaired student t test results found to be same for both 1min and 5min.

**P value and Statistical Significance:**

The two-tailed P value equals 0.2547
By conventional criteria, this difference is considered to be not statistically significant.

**Confidence Interval:**

The mean of Group One minus Group Two equals 0.2400000.
95% confidence interval of this difference: From -0.6557236 to 0.1757236.

**Intermediate Values used in Calculations:**

\[ t = 1.1456 \]

Standard error of difference = 0.209.

**COMPARISON OF QUALITY OF ANALGESIA (Visual Analogue Pain Scale) (TABLE 11):**

<table>
<thead>
<tr>
<th></th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>1.42</td>
<td>0.34</td>
</tr>
<tr>
<td>Median</td>
<td>0.5</td>
<td>0</td>
</tr>
<tr>
<td>Mode</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Standard deviation</td>
<td>1.90692</td>
<td>1.50658</td>
</tr>
</tbody>
</table>

Table 11

Unpaired t test results.

**P value and statistical significance:**

The two-tailed P value equals 0.0022.
By conventional criteria, this difference is considered to be very statistically significant.

**Confidence Interval:**

The mean of Group One minus Group Two equals 1.0800000.
95% confidence interval of this difference: From 0.3979590 to 1.7620410.

**Intermediate Values used in Calculations:**

\[ t = 3.1424 \]

Standard error of difference = 0.344.
It indicates the parturients of group-2 had better quality of analgesia than group-1 parturients.

Comparison of Mode of Delivery (Table 12): Mode of delivery was recorded as normal spontaneous vaginal deliveries, vaginal deliveries, vaginal deliveries with instrumental intervention and caesarean section are tabulated as follows.

<table>
<thead>
<tr>
<th>Mode of Delivery</th>
<th>Group-1</th>
<th>Instrumental Deliveries</th>
<th>Group-2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous Vaginal</td>
<td>40(80%)</td>
<td>8(16%)</td>
<td>43(86%)</td>
</tr>
<tr>
<td>Deliveries</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Caesarean Deliveries</td>
<td>2(4%)</td>
<td></td>
<td>2(4%)</td>
</tr>
</tbody>
</table>

Table 12

The instrumental deliveries were found to be less in group-2 parturients compared to group-1 parturient.

DISCUSSION: Labor pain is a subjective experience with sensory and emotional components. Epidural analgesia using low concentration of local anesthetic and newer opioids, gained wide popularity as safe and effective technique of pain relief during labor.

Opioids as epidural adjuvants to LA improve the quality of the block and provide a dose-sparing effect. The present clinical study is undertaken to compare Bupivacaine and fentanyl v/s Bupivacaine and Butorphanol in relieving the pain and its effect on neonatal outcome.

A total number of 100 parturients, all primigravidae belonging to ASA1-2 were selected and randomly divided into 2 groups of 50 each.

Group-1 n =50. This group received 0.1% Bupivacaine 10ml plus Fentanyl 0.0002% as initial dose and 0.1% bupivacaine 10ml with Fentanyl 0.0002% as top up doses. Group-2 n=50. This group received a combination of 0.1% bupivacaine 10ml plus butorphanol 1mg as initial dose and 0.1% Bupivacaine 10ml as top up doses.

The parameters observed and statistically analyzed were onset of analgesia, duration of analgesia with loading dose, total number of doses required during the labor, APGAR scores at 1min, 5 min and expression of parturients regarding pain relief. Other parameters like pulse rate, blood pressure, respiratory rate, temperature, SpO2, fetal heart rate, level of sensory block and level of motor block and side effects, if any, are noted. The pain relief was assessed using VISUAL ANALOGUE PAIN SCALE consisting of 0-10cm with no pain and worst pain at both ends.

ONSET OF ANALGESIA is the only disadvantage with butorphanol group, since in our study in group-1 the onset of sensory blockade is faster when compared to that in the group -2, when it was statistically analyzed by students 't' test, the p value is <0.0001 i.e., significant. The faster onset of action in group-1 could be due to fentanyl high lipid solubility compared to Butorphanol in Group-2. With regard to onset of analgesia, the group - 1 is comparable to authors like Reynold et al and Group-2 comparable to Chestnet et al.

DURATION OF ANALGESIA WITH 1st DOSE is the major advantage with Butorphanol group, since the mean duration of analgesia with 1st dose in group -2 [92.16±14.24] is more than that seen in the group-1 [68.68±9.19]. When it was statistically analyzed by students 't' test the p value is <0.0001,which is statistically significant. The longer duration in group -2 could be due to lesser...
systemic absorption of butorphanol which has less lipid solubility. The duration of analgesia seen in group-1 is comparable to authors Reynold et al and price et al. Group-2 showed results similar to studies done by Hunt et al, 1989 and Rodriguez et al 1990.

The requirement of top up doses is also significantly less in the group -2 when compared to that in the group-1, when analyzed by students ’t’ test the P value is <0.0001, which is significant. In other words, Butorphanol reduced the total dose of Bupivacaine requirements by reducing number of doses.

The total time duration from injection of drug to delivery was in Group-1[302.9±42.92], Group-2[290.18±47.49] in our study. When it was analyzed statistically the p value is >0.5 which is not statistically significant.

QUALITY OF ANALGESIA is more in group-2 compared to group-1 as assessed by visual analogue scale, which could be due to additional action of butorphanol in group-2 on Mu1, Mu2 along with K receptors. The student t test gives the p value of 0.0022 which is statistically significant and indicates that the group-2 had better analgesia than group-1. All this observations correlate well with previous studies of Hunt et al, 1989, Tank TK, Ann Acad. Med. Singapore, 1998 27(2), David H Chest nut, (American Family Physician Nov. 15, 1998).

When the mode of delivery in both the groups was compared, the requirement of instrumental intervention and caesarian section were almost similar in both the groups. When these results were analyzed by student ’t’ test the P value >0.5, which was not statistically significant. The indications for caesarian section in the parturients studied were cord around the neck, cord prolapse, fetal distress.

The neonatal outcome was assessed with APGAR scoring at 1min and 5min. In most of them the APGAR scores at 1min were between 7and 8 in both groups except in one neonate in Group -2 who had fetal distress due to cord around the neck during delivery. But the APGAR scores at 5 min were between 9 and 10 indicating lack of clinically relevant respiratory depression and depressed neurobehaviour scores in neonates.

Because of the addition of Butorphanol parturients got sedated but were arousable, with increased quality of analgesia which made them to accept the procedure better than those in the Group-1. Addition of Butorphanol had no effect on the uterine contractions and there was no increase in the number of instrumentation and caesarian section. And there was also no significant difference in the motor blockade compared to Group-1.

All the results clearly indicate that addition of a low dose of opioid like Butorphanol 1mg to 0.1 % Bupivacaine increased quality of analgesia, duration of analgesia and the requirement of top up doses is very much reduced.

This is very advantageous in promoting obstetric analgesia as there was no significant incidence of neonatal asphyxia as revealed by APGAR scoring.

**CONCLUSION:** From this study it may be concluded that using a combination of 0.1% Bupivacaine with 1mg Butorphanol during epidural analgesia for labour provides excellent pain relief, prolonged duration of action with simultaneously decreasing the top-ups required, thereby reducing the total local anesthetic requirement compared to 0.1% bupivacaine with 0.0002% fentanyl [20mcg].
BIBLIOGRAPHY:

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