EFFECT OF LABOUR ANALGESIA IN TERM SINGLETON PREGNANCIES AND ITS OBSTETRIC OUTCOME

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Abstract

Background: Pain during childbirth to a mother is very severe and most of them endure that pain in their lifetime. With the advent of new techniques and skilled practitioners, it is possible to relieve pain during labour. Epidural analgesia is the gold standard technique in providing labour analgesia. Materials and Methods: This prospective randomised comparative study was done in the Department of Obstetrics and Gynaecology, Govt. General Hospital, Guntur Medical College, Guntur, over a period of two years. Two different types of combined spinal epidural type of labour analgesia were administered to two separate groups and studied. Result: The two study groups showed similar demographic data. The mean first-stage and second-stage duration in both groups are comparable. There is no significant difference in maternal vital signs, fetal heart rate and incidence of instrumental deliveries in both groups. There was significant pain relief with excellent patient satisfaction. Conclusion: Neuraxial anaesthesia is the safest and most commonly used. Among them, combined spinal and epidural analgesia is the most preferred method.

INTRODUCTION

Labour pain is an emotional ride, a mother experiences in her lifetime which involves both physiological and psychological changes. Labour pain is one which is ranked at the top in the pain rating scale compared to other pains that are experienced by women. Since that of providing pain relief during labour is surrounded by myths as religious mores of 19th century regard pain including labour pain as divine punishment, any involvement in relieving that pain was considered immoral.[1] Labour analgesia still remains an ongoing challenge in modern obstetrics. The “birth” of obstetric anaesthesia started with the introduction of ether by obstetrician James Youn Simpson in 1847.[2,3] Local anaesthetics are introduced into the epidural space that leads to numbness of nerves and pain sensation without effecting the mother’s ability to move called as walking epidural anaesthesia.[4,5]

Aims and Objectives

Aim of the study is to determine the maternal and fetal outcome comparing with 10ml of 0.125% BUPIVACAINE + 2mcg /ml FENTANYL and 0.1% ROPIVACAINE + 2 mcg /ml FENTANYL by dividing the study population into 2 groups using COMBINED SPINAL EPIDURAL type of labour analgesia.

1. To study the effectiveness of relieving the pain during labour comparing two drugs in two groups.
2. To study incidence of mode of delivery-normal, instrumental or caesarean section deliveries using two different drugs in two groups.
3. To study the duration of stages of labour in between 2 groups using two different drugs.
4. To study the consequence of combined spinal epidural labour analgesia on the fetal outcome along with intrapartum fetal monitoring at 1 minute and 5-minute APGAR scores using two different drugs in between two groups.

MATERIALS AND METHODS

Present study is a prospective randomised comparative study done from December 2019 to January 2021 at GGH, Guntur on 60 full term primigravida and multi gravida parturient women of...
ASA status I & II who fits into the inclusion criteria. Using 10 ml of 0.125% bupivacaine + 2mcg/ml fentanyl and 0.1% Ropivacaine + 2 mcg/ml fentanyl by dividing the study population into 2 groups using combined spinal epidural type of labour analgesia on maternal anf fetal outcome.

**Inclusion Criteria**
Pregnant woman with term singleton pregnancy with cephalic presentation, in first stage of labour with informed and written consent
1. With regular antenatal checkups
2. With no obstetric or non obstetric risk factors
3. Age: 19-30 years
4. Height >150cms
5. Weight >55kgs
6. BMI 18-25kgs/m2

**Exclusion Criteria**
1. Patient refusal
2. Mothers with co-existing diseases such as Diabetes, Chronic Hypertension, PIH, Bronchial asthma, IHD, valvular heart diseases, previous LSCS
3. Spine abnormalities with local skin infections
4. Coagulopathies
5. Twin or triplet gestation
6. Neurological or neuro muscular disorders
7. Thrombocytopenia
8. Cephalo pelvic disproportion
9. Preterm gestation

**Monitoring**
1. Maternal heart rate, Blood pressure, VAS was monitored every 5 mins for first 30 mins, every 15 minutes for 1st one hr and every 60 mins till delivery was done.
2. Onset of analgesia is time from drug administration to VAS <3
3. Top up dose upto 8ml given when VAS score is >4
4. Prior to each top up dose - Heart rate , level of block, maternal pulse, BP recorded.
5. Augmentation with oxytocin infusion.
6. During contractions maternal pain severity assessed with VAS (visual analog scale).

**Time of Onset of Analgesia:** Time taken for achieving visual analogue scale less than 3. The patient is asked to point the position on the line between faces on the scale to indicate how much pain they are currently feeling. The far Right indicates WORST PAIN EVER & far left indicates NO PAIN.

**Visual Analog Scale**
Unidimensional measure of pain intensity. Contains horizontal line of 10cms anchored by 2 verbal descriptors 1 for each symptom extreme. Patient was asked to place a finger over the scale according to intensity of pain felt by her.

Using ruler, score is determined by distance on 10cms line between no pain and patients mark.

**Cutoff Points**
1. No pain (Excellent satisfaction): 0–4mm
2. Mild pain (Good satisfaction):5-44mm
3. Moderate pain (Average satisfaction) :45-74mm
4. Severe pain (poor satisfaction): 75-100mm

Level of Sensory Blockade assessed using spirit cotton for loss of cold sensation in midclavicular line bilaterally from nipple to pubic symphysis.

**Modified Bromage Scale:** used to assess the motor blockade
0. >No motor blockade.
1. >unable to lift leg straight.
2. >Unable to flex knees.
3. >unable to flex ankles.

Sedation Was assessed by 5 point scale.
0. Wide awake.
1. Drowsy.
2. Dozing eyes shut intermittently.
3. Asleep.
4. Unarousable.

Statistical analysis was done using spss version 17 for windows. Two-sided independent student’s t tests to analyse continuous data and chi square test for association was used to compare the categorical variables between treatment allocations. P<0.05 was considered as statistically significant.

**RESULTS**
In the present study by mean age among Group A was 21.8±1.68 in Group B was 21.70±2.11.
Majority i.e., 60% belong to 19-22 years age followed by 36.7% belong to 23-26 years age, 33% belong to 27-29 years. Among Group A 60% belong to 19-22 years, 40% belong to 23-26 years. In Group B 60% belong to 19-22 years, 33.3% to 23-26 years, 6.7% belong to 27-29 years. There is no statistically significant difference between both groups as calculated P value is >0.05.

<table>
<thead>
<tr>
<th>Table 1: Age Distribution</th>
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<tbody>
<tr>
<td>Group A (n=30)</td>
</tr>
<tr>
<td>N</td>
</tr>
<tr>
<td>19 – 22</td>
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<tr>
<td>23 – 26</td>
</tr>
<tr>
<td>27 – 29</td>
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<tr>
<td>Total</td>
</tr>
<tr>
<td>Mean ± SD</td>
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</tbody>
</table>

Chi square test = 2.18, p=0.33, Not statistically significant

In present study, 90% are primigravida’s & b10% are multi’s. Group A has 83.3% primis and 16.7% multi’s. Group B has 96.7% primi’s and 3.3% multis. There is no statistically significant difference between two groups as calculated P value is >0.05.

<table>
<thead>
<tr>
<th>Table 2: Primigravida/Multigravida</th>
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</thead>
<tbody>
<tr>
<td>Group A (n=30)</td>
</tr>
<tr>
<td>N</td>
</tr>
<tr>
<td>Primigravida</td>
</tr>
<tr>
<td>Multigravida</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Chi square test = 2.91, p=0.08, Not statistically significant

In present study, 90% are primigravida’s & b10% are multi’s. Group A has 83.3% primis and 16.7% multi’s. Group B has 96.7% primi’s and 3.3% multis. There is no statistically significant difference between two groups as calculated P value is >0.05.

<table>
<thead>
<tr>
<th>Table 3: Vitals</th>
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<tbody>
<tr>
<td>Group A (n=30)</td>
</tr>
<tr>
<td>Mean</td>
</tr>
<tr>
<td>PR</td>
</tr>
<tr>
<td>SBP</td>
</tr>
<tr>
<td>DBP</td>
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</tbody>
</table>

In relation to Pulse rate, Systolic and diastolic blood pressure there was a statistically significant difference in between two groups as p value is <0.05.

<table>
<thead>
<tr>
<th>Table 4: Duration of labour in minutes</th>
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<tbody>
<tr>
<td>Group A (n=30)</td>
</tr>
<tr>
<td>Mean</td>
</tr>
<tr>
<td>Stage I</td>
</tr>
<tr>
<td>Stage II</td>
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<tr>
<td>Stage III</td>
</tr>
</tbody>
</table>

In present study, mean duration of first stage labour in Group A was 173±20.37 in Group B was 177.93± 25.85. The mean duration of second Stage labour in Group A was 31.56± 5.7. Group B was 30.73+ 6.34. There is no statistically significant difference in between groups as P value is >0.05.

<table>
<thead>
<tr>
<th>Table 5: VRS Scale</th>
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<tbody>
<tr>
<td>Group A (n=30)</td>
</tr>
<tr>
<td>Mean</td>
</tr>
<tr>
<td>0 min</td>
</tr>
<tr>
<td>60 min</td>
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<tr>
<td>120 min</td>
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<tr>
<td>180 min</td>
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Table 6: Mode of delivery

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<th>Table 6: Mode of delivery</th>
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<tbody>
<tr>
<td>Group A (n=30)</td>
</tr>
<tr>
<td>N</td>
</tr>
<tr>
<td>Normal delivery</td>
</tr>
<tr>
<td>Instrumental</td>
</tr>
<tr>
<td>LSCS</td>
</tr>
<tr>
<td>Total</td>
</tr>
</tbody>
</table>

Chi square test = 2.91, p=0.08, Not statistically significant
In present study, 90% patients underwent Spontaneous vaginal delivery and 10% had instrumental delivery. In Group A 25 patients had SVD and 5 patients had instrumental delivery. In Group B, 29 delivered by SVD and 1 patient delivered by instrumental delivery. There is no statistically significant difference between groups as P value is .0.05.

Table 7: APGAR Score

<table>
<thead>
<tr>
<th></th>
<th>Group A (n=30)</th>
<th>Group B (n=30)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>APGAR at 1 min</td>
<td>Mean 8.76, SD 0.43</td>
<td>Mean 7.74, SD 0.41</td>
<td>0.99</td>
</tr>
<tr>
<td>APGAR at 5 min</td>
<td>Mean 8.76, SD 0.43</td>
<td>Mean 8.77, SD 0.42</td>
<td>0.94</td>
</tr>
</tbody>
</table>

In present study, Group A mean APGAR @ 1 minute and 5 minutes is 7.76±0.43 and 8.76±0.43 and in Group B APGAR @ 1 minute and 5 minutes is 7.74±0.41 and 8.77±0.42. There is no statistically significant difference between groups as P value is >0.05.

Table 8: Patient satisfaction

<table>
<thead>
<tr>
<th>Patient satisfaction</th>
<th>Group A (n=30)</th>
<th>Group B (n=30)</th>
<th>Total (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Average</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Good</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Excellent</td>
<td>30(100%)</td>
<td>30(100%)</td>
<td>60(100%)</td>
</tr>
<tr>
<td>Total</td>
<td>30(100%)</td>
<td>30(100%)</td>
<td>60(100%)</td>
</tr>
</tbody>
</table>

In present study all participants have expressed their satisfaction as Excellent.

DISCUSSION

Use of epidural analgesia has rapidly increased almost tripled between 1980-2001. About 60 % of Parturients are using analgesia during labour currently in United States. About 20% Parturient women in Wales and England received epidural analgesia. The National average acceptance of epidural analgesia in a developing country like India is almost negligible though sporadically few centre have a comprehensive labour analgesia program.[6,7]

At times, it is associated with adverse effects on both maternal and fetal physiology. The stress of labour can cause maternal hyperventilation and increased catecholamine concentration which might result in maternal and foetal hypoxemia. Thus, to avoid such an adverse effect of pain during labour an effective and safe labour analgesia has been considered in the recent times.

Casati et al,[8,9] compared the same techniques in 120 non obstetric patients. They found that lower hypotension, lower incidence of spinal impairment, and it took less time to practise in different needle classes. This is why we used the separate CSE needle technique in our research.

Age distribution

The Present study, mean age in Group A is 21.8 and in Group B is 21.7. In the study done by Antanakou A et al 10, the mean age of the participants was observed to be 25.9 ± ± years. The mean age observed in the present study was in near consonance with the Present study.

In the study conducted by Silva YAP et al,10,11 The study population had a mean age of 24.2 years ± SD (± 6.4), ranging from 13 to 45 years.

PARITY: In present study,90% are primigravida’s & 10% are multi’s.
VITALS - The mean PR of the participants who received epidural analgesia was 87.73±6.63 bpm, and the mean PR in the control group was 77.30±3.24. There was a statistically significant difference across the groups and the mean PR of the patients who received epidural analgesia was significantly higher when compared to the control groups.

In the studies done by Antanakou A et al.[12,13] and Silva YAP et al.[14] has also observed similar sort of changes in the patterns of vitals and the observations made are in consonance with the present study.

DURATION OF LABOUR: In present study, Mean duration of first stage labour in Group A was 1732 ± 0.37 in Group B was 177.932 ± 5.85. The mean duration of second stage labour in Group A was 31.56 ± 5.7 and Group B was 30.73 ± 6.34 and third stage is 5mins in both groups. There is no statistically significant difference in between groups as P value is >0.05

Sharma et al.[15] in their study concluded that low dose epidural analgesia does not significantly prolong the labour in second stage (30 to 90 min). Saunders et al,[16] have concluded that oxytocin acceleration shortens the second stage of labour in epidural analgesia.

Bawande et al.[17] in their study reported that the mean length of the first stage of labour was 252.83 ± 83.19 min in the (BF) and 250.33 ± 86.84 min in the (RF) category (P = 0.910). The mean length of the second stage of labour was 31 ± 13.93 min in the (BF) group and 27.73 ± 3.94 min in the (RF) group (P = 0.221) the duration of labour at all stages was comparable between two groups.

CTG findings

The CTG finding did not show any significant difference across the groups who received Combined Spinal Epidural Analgesia with Bupivacaine and Fentanyl. Ropivacaine plus Fentanyl. In the study conducted by Sharma S et al.[18] it was observed that although epidural analgesia was not associated with increased caesarean deliveries.

Maternal outcome:

VRS:

Pain relief is an integral part of labour management. Epidural analgesia is the most effective method for the control of pain during labour but irregularity of analgesia, toxicity of local anaesthetics (LA) are the major limitations. Epidural analgesia provides effective control of labour pain. In the present study based on VAS a 160 and VAS at 210 showed a statistically significant difference between observed between the 2 groups as per value calculated to be less than 0.05.

In our study, results indicate that 0.1 per cent ropivacaine and 0.1 per cent bupivacaine are compatible with mean hourly drug usage, pain VAS ratings, ether swab sensory levels, and overall patient satisfaction. Additional studies investigating the relative efficacy of ropivacaine and bupivacaine in the clinical setting are required.

Patil et al.[19-21] in their study reported that the mean VAS score at 0 min during the postoperative period was similar in both classes. With the progression of the infusion, it decreased gradually. This is similar to the results documented in previous studies. In present study, Majority of patients in both groups has no pain after administration of analgesia with respective drugs and were satisfied with effective labour analgesia rated that they had EXCELLENT pain relief with VERBAL RATING SCALE.

Mode of Delivery

The 2011 Cochrane review on epidural versus non-epidural or no analgesia in labour showed that epidural analgesia was associated with an increased risk of assisted vaginal birth. However, we found that the incidence of instrumental delivery was not significantly different (CSE, 9.0% versus Non-CSE, 12.7%). This was in contrast to earlier studies which reported higher rates of instrumental delivery in epidural compared to parenteral opioids or entonox.

In our study, no untoward effects were noted on progress of labour in patients with oxytocin augmentation.

In a study by Eriksson et al there was no clear association between frequency of epidural block and cesarean section and instrumental delivery.[22] In the study conducted by Antanakou A et al.[23-25] the indications for an instrumental delivery were prolonged second stage (36.4%), cardiotocographic (CTG) abnormalities (36.4%), maternal exhaustion (15.2%).

The use of an epidural analgesia was independently associated with the odds of an instrumental vaginal delivery (OR = 3.63; 95% CI: 2.51–5.24). Halpern and Walsh performed a meta-analysis, comparing Bupivacaine and Ropivacaine for labor epidural analgesia.[26] They found that there was no substantial difference in the occurrence of spontaneous vaginal delivery and that the mode of delivery was identical between two.

APGAR SCORES: In present study, Group A mean APGAR @ 1minute and 5 minutes is 7.76+0.43 and 8.76+0.43 and in Group B APGAR @ 1minute and 5 minutes is 7.74+0.41 and 8.77+0.42. There is no statistically significant difference between groups as P value is >0.05. This is in line with the Cochrane review in 2011 which reported that there were no significant differences in neonatal APgar scores at 5 minutes in babies born to women with epidural analgesia.[27]

Complications: In present study, Pruritus was the complication observed in about 66.7% patients. In Group A, 76.7% and in Group B 56.7% had complication observed in about 66.7% patients. Patil et al administered 0.125% Ropivacaine and 0.125%
Bupivacaine with Fentanyl 2 µg/ml for labor analgesia and found Both medications are reliable as shown by mean hourly drug usage, sensory pin pricking levels, and overall patient satisfaction.

CONCLUSION

The inference of this study is that quality of Combined Spinal Epidural analgesia which was assessed by adequate analgesia throughout labour till delivery. Both are safe also very effective drugs with preservation of motor function of lower limbs. The onset of analgesia is comparable in both groups. Combined Spinal Epidural analgesia did not have any adverse effect on the foetal outcome but shown to have a good effect on maternal outcomes. No significant changes in APGAR Scores, Fetal heart rate, Maternal vital signs with CSE analgesia in between both the groups.

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17. Bawdane KD, Magar JS, Tendolkar BA. Double blind comparison of combination of 0.1% ropivacaine and fentanyl to combination of 0.1% bupivacaine and fentanyl for extradural analgesia in labour. J Anaesthesiol Clin Pharmacol 2016;32:38-43.
27. The Cochrane Database Systemic trials 2012 have emphasized that epidural analgesia had no statistically significant impact on the risk of caesarean section.