Study of efficacy, safety and cardiotocographic changes during epidural analgesia with ropivacaine in labour

Jyoti Sharma1, Mansi Gandhi2 and Mrugank Bhavsar3

1Assistant Professor, Department of Obstetrics & Gynecology, SBKS MI & RC, Sumandeep Vidyapeeth, Vadodara, India
2Resident, Department of Obstetrics & Gynecology, SBKS MI & RC, Sumandeep Vidyapeeth, Vadodara, India
3Resident, Department of Anesthesiology, SBKS MI & RC, Sumandeep Vidyapeeth, Vadodara, India

* Correspondence Info:
Dr. Jyoti Sharma,
Assistant Professor,
Department of Obstetrics & Gynecology,
SBKS MI & RC, Sumandeep Vidyapeeth, Vadodara, India
E-mail: drgaurav2001@yahoo.in

Abstract

Background: Epidural analgesia during labour provides effective pain relief along with better maternal and neonatal outcome. Our aim of the study is to check safety and efficacy of Ropivacaine during labour analgesia. We have also compared cardiotocographic changes in labour with versus without epidural analgesia.

Material & Methods: 60 Antenatal cases in between 37-41 weeks of pregnancy in active labour were selected for study. They were randomly divided into 2 groups: Study Group (Group-1): Patients who received epidural ropivacaine for pain relief. Control Group (Group-2): No analgesia was given for pain relief. Epidural catheter was inserted in study group. They were observed for degree of pain relief, requirement of analgesia, intrapartum cardiotocographic changes and maternal tolerability and safety in terms of side effects. They were also asked for their satisfaction towards epidural analgesia.

Observation & Results: We have observed better intrapartum cardiotocographic findings with epidural analgesia. Degree of pain relief was also significantly better with epidural group. Requirement of Top-up doses and duration of rescue analgesia was better with epidural. No significant maternal or fetal side effects were noted with epidural. Patient satisfaction was definitely better with Epidural analgesia.

Conclusion: Ropivacaine in epidural is safe and effective and efficacious with better cardiotocographic findings.

Keywords: Epidural analgesia, Ropivacaine, Cardiotocography

1. Introduction

The delivery of the infant in to the arms of a conscious and pain free mother is one of the exciting and rewarding moments in medicine. Thus in today's age we can help most of women who have access to health care to make their labor less painful and just a wonderful memory of the birth of their child.

Pain relief is important because when a woman in labor starts hyperventilating (breathing excessively) during contraction, the subsequent hypoventilation (decreased breathing) causes a decreased oxygen supply to her baby. So for adequate oxygenation of the baby a mother should be relaxed during their contraction.

Epidural analgesia simply implies that labour pain relief is achieved as a result of medication administered in to the epidural space, which temporarily interrupt the transmission of labour pain. The advantage of epidural analgesia is that it provides superior pain relief during first and second stages of labor, lowering stress level, maintaining acid base balance,
uteroplacental perfusion and lowering the BP in pre-eclamptic patients, facilitates patients co-operation during labour and delivery, provides anesthesia for episiotomy & forceps delivery, allows extension of anesthesia for cesarean delivery, avoids opioid-induced maternal and neonatal respiratory depression\(^1\).

Ropivacaine is a new long acting amide closely related in structurely to bupivacaine & mepivacaine. The pharmokinetic and pharmodynamic property of ropivacaine resemble of that of bupivacaine but however ropivacaine has a lower CNS and cardiotoxic potential & less Intense motor block than bupivacaine.

Electronic fetal monitoring in labour was introduced with an aim of reducing perinatal mortality and cerebral palsy. The initial response to chronic hypoxia is to increase cardiac output and redistribution of this to heart and brain. The increase in cardiac output is achieved by an increase in heart rate. This may be followed by a reduction in fetal heart rate variability due to brainstem hypoxia. If continued a worsening hypoxia will eventually produce myocardial damage and heart rate deceleration. So electronic fetal monitoring is used throughout the labour to early detect and treat fetal compromise.

Our aim of the study is to check safety and efficacy of Ropivacaine during labour analgesia. We have also compared cardiotocographic changes in labour with versus without epidural analgesia.

2. Material & Methods

After institutional ethical approval and written informed consent for epidural labor analgesia, 60 Antenatal cases in between 37-41 weeks of pregnancy in active labour were selected for study. They were randomly divided into 2 groups:

Study Group (Group-1): Patients who received epidural ropivacaine for pain relief.

Control Group (Group-2): No analgesia was given for pain relief.

2.1 Inclusion Criteria

i) Both primipara and multipara women.

ii) Patients who were in established active stage of labour

   · Uterine contraction 2 per 10 minutes, lasting for 30 to 40 seconds.

   · Cervical dilatation was >3 cm.

iii) Patients with vertex & singleton pregnancy

iv) The patients willing for analgesia.

v) Patients with reactive non stress test

vi) Patients with informed consent

2.2 Exclusion Criteria

i) Patients with malpresentations

ii) Patients with cephalopelvic disproportion

iii) Previous caesarean delivery

iv) Patients with any medical complications (Diabetes, asthma, primary pulmonary hypertension, hypertensive disorders of pregnancy etc.)

v) Patients having antepartum haemorrhage

vi) Mothers with anticipated difficult airway and where there were more chances of operative delivery such as in conditions of short neck, diseases of larynx, goiter, and dental problem.

vii) Any neurological condition where rise in intracranial tension during delivery is anticipated such as meningitis, cancer, brain abscess, brain haemorrhage and head injury.

viii) Patients not willing for analgesia.

They were pre-hydrated with 500 ml of Ringer's lactate solution before they were subjected to epidural analgesia to reduce the incidence of maternal hypotension or foetal heart rate disturbances. Patients were laid in left lateral position with back at the edge of the table. Sitting position was an alternative especially in obese parturient as location of epidural space was easier. Under strict aseptic precaution, epidural needle was inserted in either L2/3 or L3/4 space. Epidural space was identified by using “hanging drop” method. Catheter was inserted and fixed.
Analgesia was administered when cervical dilatation is 3 cm or contractions 2/10 minutes lasting labour was well established i.e. more with strong uterine about 30 to 40 sec. Injections into the epidural space during contractions were avoided and was given in between contractions so as to avoid the risk of increased spread. The top-up dose was given on patients demand. After each top-up dose five minutes blood pressure recordings were made for the next 20 minutes and between these periods 30 minutes recording of blood pressure was maintained.

They were observed for timing for onset of analgesia, time between epidural injection and time when patient first demanded additional analgesic, No. of Top up doses and total duration of analgesia.

Maternal monitoring was done in terms of systolic blood pressure, pulse rate every five minute for first 30 minute and then every 30 minute until delivery. Degree of pain relief was evaluated immediately after the last contraction with a visual analogue score scale before the first epidural injection and at 30 minutes, 1 hour, 2 hour. Lower limb motor block was checked at every 10 minutes using the modified Bromage scale.

Fetal condition was observed carefully by cardiococgraphy. In case of fetal bradycardia/tachycardia, top up doses were not given and the patient was managed accordingly.

2.3 Cardiotocography

Cardiotocography was done at the time of admission and was reapeated at half hourly intervals in the first stage and continuous in second stage, it was performed by using the PHILIPS AVALON FM 20 maternal/fetal monitor. Ultrasound Transducer applied to the abdomen over the area of maximum fetal heart rate by using aquasonic jelly used for monitoring fetal heart rate, operate at a frequency of 2.0 MHz. Tocotransducer applied to the fundus of uterine to record the uterine activity ((without aquasonic jelly). Fetal heart rate was measured by using ultrasound transducer. Uterine activity measured externally, with the use of tocotransducer.

The patient was placed in semi-fowler's position (30°) to avoid compression over the vena cava and supine hypotension syndrome with resultant impaired uterine blood flow which may be the cause of late deceleration.

We have assessed the effect of the drug on progress of labor as well. Obstetric Outcome and neonatal outcome was also compared in both the groups. We have also observed maternal side effects such as Dryness of mouth, Nausea or vomiting, Pruritus, Hypertension/Hypotension, Drowsiness, palpitation and Post delivery complications like Backache, Headache, Paraesthesia, Time of spontaneous urination etc. We have also asked the patients for Patient's satisfaction. Global rating of analgesic effect and pain relief was assessed after 24 hours and rated such as Excellent, Good, Average and Poor.

2.4 Statistical Analysis

All data were analyzed by using paired and unpaired t-test by using scientific software. Data were presented as percentage or mean ± SD. P<0.05 was considered as statistically significant.

3. Observation & Results

All 60 patients of both the groups recruited in the study were analyzed and following data were observed.

Table 1: Demographic Profile

| Demographic Parameters | Epidural Group | Control Group | P value |
|------------------------|----------------|---------------|---------|
| Age (years)            | 23.60 ± 3.43   | 23.43 ± 2.56  | P<0.05  | NS     |
| Weight (kg)            | 52.8 ± 3.5     | 52.6 ± 3.37   | P<0.05  | NS     |
| Height (cm)            | 154.9 ± 3.94   | 156.43 ± 3.39 | P<0.05  | NS     |
| Gestational Age (weeks)| 39.3 ± 2.18    | 39.03 ± 1.19  | P<0.05  | NS     |
| Fetal Heart Rate       | 140.67 ± 15.265| 142.67 ± 14.360| P<0.05  | NS     |
| Maternal Heart Rate    | 84.6 ± 3.86    | 83.07 ± 3.53  | P<0.05  | NS     |
| Maternal Systolic BP   | 124.20 ± 4.47  | 124.53 ± 3.44 | P<0.05  | NS     |
| Maternal Diastolic BP  | 86.40 ± 3.91   | 85.07 ± 3.40  | P<0.05  | NS     |
Table 2: Intraoperative Cardiotocographic Findings

| Cardiotocographic findings | Epidural Group | Control Group |
|----------------------------|----------------|---------------|
| a) Fetal Heart Rate (bpm)  |                |               |
| 110-160                    | 26 85.67       | 28 93.33      |
| >160                       | 03 10          | 02 6.67       |
| <110                       | 1 3.33         | -             |
| b) Beat to beat variability|                |               |
| 5-25                       | 29 96.67       | 30 100        |
| <5 (for 40-90 minutes)     | 1 3.33         | -             |
| <5 (for >90 minutes)       | -              | -             |
| c) Absence of Acceleration | 1 3.33         | -             |
| d) Presence of deceleration|                |               |
| Early                      | 4 13.33        | 2 6.67        |
| Late                       | 0 -            | 0 -           |

Table 3: Cardiotocographic findings according to NICE Guidelines

| CTG Findings (Intrapartum) | Epidural Group | Control Group |
|----------------------------|----------------|---------------|
| Normal                     | 25 83          | 27 90         |
| Suspicious                 | 5 17           | 3 10          |
| Pathological               | -              | -             |
| Total                      | 30 100         | 30 100        |

Figure 1: Time required for onset of analgesia

Figure 2: Degree of Pain Relief in Epidural Group

Figure 3: No. of top-up doses required in epidural group
Table 4: Maternal Side Effects

| Side effect    | Epidural Group | Control Group | P value |
|----------------|----------------|---------------|---------|
|                | No.  | %   | No.  | %   |         |
| None           | 15   | 50  | 20   | 67  | P<0.05  |
| Nausea Vomiting| 6    | 20  | 4    | 13  | P<0.05  |
| Dry Mouth      | -    | -   | 2    | 7   | P<0.05  |
| Palpitation    | -    | -   | -    | -   |         |
| Drowsiness     | -    | -   | -    | -   |         |
| Hypotension    | -    | -   | -    | -   |         |
| Headache       | 2    | 7   | 2    | 7   | P<0.05  |
| Pruritus       | 2    | 7   | -    | -   |         |
| Backache       | 3    | 10  | 2    | 7   | P<0.05  |

4. Discussion

Use of epidural analgesia has gained popularity in many obstetric clinics. Uterine contraction leads to an increase in catecholamine level of pregnant woman in labour. Fine gold-H, Modell-G, 2000 had seen that use of epidural analgesia during labour decreases the catecholamine level. All sensoryafferent can be suppressed by administrating a local anaesthetic via a lumbar catheter.

Ropivacaine and bupivacaine are the most commonly used local anaesthetic agent in local analgesia. In literature Ropivacaine have been administered at variable doses either as bolus or as continuous epidural infusion. In our study we have administered 10ml of 0.1% of ropivacaine as bolus injection. Ropivacaine provides analgesia with less motor block compare with Bupivacaine (Writer et al\(^2\)). Ropivacaine produces less motor block of A-fibre or a similar degree of block of sensory fibre.

In our study the fetal heart rate was found in normal range (110-160 bpm) In 85.67% cases in epidural group and 93.33% in control group while 10% cases had fetal heart rate >160 bpm and 3.33% cases have foetal have rate < 110 bpm in epidural group. While only 6.67% cases have > 160 bpm foetal heart rate in control group. 96.67% cases in epidural group had normal baseline variability [5-25 bpm] while only 3.33% cases have < 5 baseline variability in epidural group. Absence of acceleration was found in 3.33% cases in epidural group while in control group all cases had normal beat to beat variability and none of cases had absence of acceleration. Early decelerations were seen in 4[13.33]\% cases in epidural group while in control group they were found in 2[6.67]\% cases. In literature the study done by Medge et al\(^2\), one case of foetal bradycardia was found which was managed by Ephedrine. Moorie et al 1995, 3 cases of foetal bradycardia were found but none of case was shifted for operative intervention [i.e. change in foetal heart rate were not significantly] Rudolf Steinstro et al\(^4\); according to this study no abnormal cardiotocographic findings were seen.

According to NICE Guidelines in the present study it was found that 83% cases had normal CTG tracing during whole intrapartum period in epidural group while 17% cases had suspicious CTG finding in whole intrapartum, period in epidural group. None of case in both the groups had pathological CTG tracing and on statistically analyzing the interpretations no significance was noted.
Time for onset of analgesic action after epidural Ropivacaine was 13.13 ± 4.33 minutes which is almost comparable with the following studies. The mean Visual Analogue Score (VAS) at '0' Hour, was 74.57 ± 8.06 mm while at 30 minutes and at 1 Hour it was 13.50 ± 5.89 mm and 17.17 ± 8.97 mm respectively. On comparison VAS at 30 minutes and at 1 hour was statistically significant. The mean VAS studied by different workers was comparable with our studies.

In present study no appreciable changes were recorded in pulse rate in both the groups. Similar results were obtained by Tugrul et al. No appreciable change were observed in systolic and diastolic blood pressure initially and 1 hour later in both the groups. Similar results were obtained by Tugrul et al. In epidural group 50% cases develop no side effect while in control group in 67% cases no side effects were seen. Nausea and vomiting was seen in 6 (20%) cases in epidural group and in 4 (13%) cases in control group. 2 (6.67%) cases in both the groups complained of headache and pruritus was developed in 2 (6.67%) cases of epidural group. There were 3 cases (10%) in epidural group and 2 (6.67%) cases in control group who developed backache. In our study none of case developed hypotension, drowsiness in both the groups. Medge et al. 2002 observed that 40% patient who received epidural analgesia developed hypotension and nausea in 4% cases. In our study overall satisfaction in most of patient was excellent 16 (53%) cases and good in 9 (30%), average in 5 (17%) cases. Almost similar results were seen in study done by Mouse et al. in which overall patient's satisfaction rate was excellent in 65% cases and 55% cases it was good. According to Lee et al. Good / Excellent rate was 95% as compared to our study (83%).

5. Conclusion

We concluded that use of Ropivacaine in epidural labour analgesia is safe, efficacious and with no significant cardiocotogicographic changes.

Acknowledgement

We are thankful to our patients to be a part of our study. We are thankful to the Department of Obstetrics & Gynecology, Anesthesiology and Pediatrics for their support to complete this study.

References

1. Nancy Merson. A comparison of motor block between Ropivacaine and Bupivacaine for epidural analgesia. AANA J. 2001:69:1.
2. Writer WD, Stienstra R, Eddleston JM, et al. Neonatal outcome and mode of delivery after epidural analgesia for labour with Ropivacaine and Bupivacaine: a prospective meta-analysis. Br. J. Ansth. 1998:81:713-7.
3. Medge D. Owen. Ropivacaine 0.075% and Bupivacaine 0.075% with fentanyl 2 mcg/ml are equivalent for labour epidural analgesia. Anesth. Analg. 2002;94:179-83.
4. Rudolf Stienstra, Tim A. Ropivacaine 0.25% versus Bupivacaine 0.25% for continuous epidural analgesia in Labour: A Double blind comparison anesthesia analogue 1995;80:285-9.
5. Tugrul Semih. Oral effect of epidural analgesia using Ropivacaine on mother and newborn during labour. Saudi Med. J. 2006; 27(12):1853-58.
6. Wesam F. Mousa, R.R. Al-Metwalli. Epidural analgesia during labour-0.5% Lidocaine with fentanyl vs 0.08% Ropivacaine with fentanyl. M.E.J. Anesth. 2010;20(4):980-7.
7. Bee B. Lee, FANZCA. Epidural infusions of Ropivacaine and Bupivacaine for labour analgesia: A Randomized, Double-blind study. Anesth. Analg. 2009;99:1145-52.