## EUROPEAN JOURNAL OF PHARMACEUTICAL AND MEDICAL RESEARCH

www.ejpmr.com

Research Article ISSN 2394-3211

EJPMR

# A COMPARATIVE STUDY OF PATIENT CONTROLLED EPIDURAL ANALGESIA VS CONTINUOUS EPIDURAL INFUSION IN LABOUR ANALGESIA USING ROPIVACAINE WITH FENTANYL

<sup>1</sup>Dr. Sarvesh Srivastava, <sup>2</sup>\*Dr. Shibu Sasidharan, <sup>3</sup>Brig Purnendu, <sup>4</sup>Dr. Shishir Kumar, <sup>5</sup>Dr. Babitha Shibu, <sup>6</sup>Dr. Shalendra Singh, <sup>7</sup>Dr. Suneeta Singh

<sup>1</sup>Reader, Dept. of Anaesthesiology & Critical Care, Level 3 Hospital, Goma.

<sup>2</sup>Assistant Professor, MD, DNB, MNAMS; HOD (Anaesthesia); Dept. of Anaesthesia and Critical care, Level 3 Hospital, Goma.

<sup>3</sup>Consultant Anaesthesia, Indian Army.

<sup>4</sup>Reader, Dept. of Anaesthesiology & Critical Care, 166 Military Hospital, Satwari Cantt, Jammu, Jammu and Kashmir.

<sup>5</sup>DMRD, Consultant Radiologist, Ojas Hospital, Panchkula.

<sup>6</sup>MD, DNB, DM, Associate Professor, Department of Anaesthesia and Critical Care, AFMC, Pune-411040, Maharashtra.

<sup>7</sup>MD, DNB, Head, Department of Obs & Gynecology, Level III UN Hospital, Goma.

\*Corresponding Author: Dr. Shibu Sasidharan

Assistant Professor, MD, DNB, MNAMS; HOD (Anaesthesia); Dept. of Anaesthesia and Critical care, Level 3 Hospital, Goma.

**DOI:** 10.20959/ejpmr20206-8425

Article Received on 29/03/2020

Article Revised on 19/04/2020

Article Accepted on 09/05/2020

#### **ABSTRACT**

**Background:** Epidural analgesia is considered to be most effective tool for labour analgesia. Epidural drugs are administered either by bolus, continuous infusion or by patient controlled pumps. Historically, intermittent bolus dosing of local anaesthetic by the clinician (anaesthetist, nurse or midwife) was used. However this technique had a number of drawbacks including inconsistent analgesia, potential toxicity and concerns about sterility each time the clinician opened the system to administer a bolus. PCEA has not been broadly used for labour analgesia in India and there are no reports of the comparison between PCEA and CEI for Indian parturient using Ropivacaine with Fentanyl. So this study was selected and initiated to evaluate the difference between these two commonly employed labour analgesia techniques in Indian parturients undergoing labour at a tertiary care hospital. Methods: Epidural catheter of 16/18 G was inserted at L2-3 or L3-4 space, a 10 ml loading dose of study drugs solution (0.1% Ropivacaine + 2 mcg/ml of Fentanyl) was injected. After achieving initial pain relief, parturients were randomized in to PCEA or CEI group using closed envelop technique. Parturients in PCEA group received background continuous infusion of study drug solution at 6 ml/hr and patient controlled demand bolus of 6 ml with a lockout period of 20 minutes. Parturients in CEI group received continuous infusion of 10 ml/hr with a clinician initiated bolus of 7 ml on parturients request. Clinician initiated bolus were given after an interval of 30 minutes. Results: After the initial pain relief was achieved parturients were assessed for pain relief using VAS score. In both groups, VAS score was comparable during both stages of labour. Mean VAS score in PCEA group was 2.21 (S.D-0.602) and in CEI group was 2.27 (S.D-0.711) with P value of 0.664. The incidence of motor blockade as assessed using Bromage scale was comparable in both groups. One parturient in PCEA group experienced mild motor blockade (Grade II- assigned a score of 1 out of total 3), which regressed within two hours during labour only. The mean Bromage score in PCEA group was 0.008 (S.D-0.05) and in CEI group it was 0.000 (S.D-0.000) with P value of 0.322, signifying an insignificant difference. Conclusions: Findings of our study was consistent with those of previous studies that PCEA provides superior labour analgesia as compared to CEI in terms of decreased requirement of local anaesthetics and lesser intervention by Anaesthesiologist.

**KEYWORDS:** Epidural Analgesia, Ropivacaine, PCEA, CEI.

## INTRODUCTION

Labour is a defining event in women life associated with joy, apprehension and labour pain. The level of pain experienced and effectiveness of pain relief may influence a woman's satisfaction with labour and delivery and may have immediate and long term emotional and psychological effects.

Since the historical use of ether for labour analgesia in 1847, various pharmacological and non pharmacological methods for labour analgesia have evolved, each having its own merits and demerits. But even today the hunt by medical science continues to find an ideal method for labour analgesia. To date neuraxial/regional analgesia remains the gold standard method for labour analgesia.

Epidural analgesia is considered to be most effective tool for labour analgesia. The choice of drugs and dosage varies from institution to institution. Epidural drugs are administered either by bolus, continuous infusion or by patient controlled pumps. Historically, intermittent bolus dosing of local anaesthetic by the clinician (anaesthetist, nurse or midwife) was used. However this technique had a number of drawbacks including inconsistent analgesia, potential toxicity and concerns about sterility each time the clinician opened the system to administer a bolus. Continuous epidural infusion (CEI) of local anaesthetics was introduced into common clinical practice in the 1980s. While the technique circumvented a number of difficulties, it was not ideal. Many patients still required clinician initiated top-ups and experienced unacceptably dense motor block in the lower extremities. Although many combinations of infusion rates and various concentrations of local anaesthetics and additives have been investigated, these problems persist. Patient-Controlled Epidural Analgesia (PCEA) for relief of labour pain was first described by Gambling in 1988. This technique allowed the patient to control the dose of epidural medication as labour and pain patterns changed. It also allowed for individualization of the drug dosage by the patient, allowing her to trade off therapeutic effects (e.g. complete pain relief) and side effects (e.g. motor block). However the equipment needed for PCEA may be more expensive than CEI.

PCEA has not been broadly used for labour analgesia in India and there are no reports of the comparison between PCEA and CEI for Indian parturient using Ropivacaine with Fentanyl.

So this study was selected and initiated to evaluate the difference between these two commonly employed labour analgesia techniques in Indian parturients undergoing labour at a tertiary care hospital.

## **OBJECTIVES** were to assess -

Difference in Total Drug Requirement using Mean Hourly consumption of drugs

Patient satisfaction level for quality of analgesia using VAS score

Difference in motor blockade using Bromage scale

## MATERIALS AND METHODS

This study is a Randomized Control Study conducted at a tertiary level teaching hospital. Duration of study was from January 2014 to December 2014. Based on previous study by Saito M et al, sample size was calculated after consultation with biostatistician of institute. Number of patients required to be enrolled in each group came out to be 7.

However, a sample size of 50 patients was taken in each group.

#### **INCLUSION CRITERIA**

Consenting Primigravida parturients undergoing labour who requested for pain relief Age between 18-35 yrs Parturients in ASA I and II class

## **EXCLUSION CRITERIA**

Parturients with a known history of allergy to the local anaesthetics.

Parturients with uncontrolled systemic illness, cardiac disease, eclampsia, pre-eclampsia, coagulopathies or any other disease for which parturient is in ASA III or above.

Spinal deformity, local dermatological condition. Any contraindication to the procedure or parturient unwillingness.

## PRE PROCEDURAL REQUIREMENT

Parturients briefed and consent obtained.

Intravenous access obtained and parturient preloaded with 500 ml Lactated Ringer's solution.

Non invasive blood pressure, heart rate, oxygen saturation and VAS score recorded at starting and then at hourly interval.

## LUMBAR EPIDURAL TECHNIQUE

Epidural catheter of 16/18 G was inserted at L2-3 or L3-4 space as per standard practice using LOR technique.

After careful aspiration to rule-out intravascular/intrathecal injection, a 10 ml loading dose of study drugs solution (0.1% Ropivacaine + 2 mcg/ml of Fentanyl) was injected. After achieving initial pain relief, parturients were randomized in to PCEA or CEI group using closed envelop technique.

Parturients in PCEA group received background continuous infusion of study drug solution at 6 ml/hr and patient controlled demand bolus of 6 ml with a lockout period of 20 minutes.



Figure 1: GRASEBY-3300 PCA PUMP.

Parturients in CEI group received continuous infusion of 10 ml/hr with a clinician initiated bolus of 7 ml on parturients request. Clinician initiated bolus were given after an interval of 30 minutes.



Figure 2: EMCO INFUSION PUMP.

Parturients were monitored continuously and various parameters were observed. All the parameters were entered in the case report chart.

#### **DATA ANALYSIS**

Data collected was compiled and analyzed using appropriate statistical tests.

#### RESULTS

The study was conducted at a tertiary level teaching hospital to assess the superiority among two tools of labour analgesia. A total of 100 parturients who qualified, were enrolled in the study and randomized into Patient Controlled Epidural Analgesia (PCEA) or Continuous Epidural Infusion (CEI) groups using Closed Envelop Technique. Epidural Analgesia was started when patients requested for the pain relief. Most of the patients had cervical dilation of 03 cm to 05 cm when they requested for pain relief.

All baseline characteristics were comparable in both groups. Initial pain score was 5/10 to 7/10 in both groups. After initial pain relief was established, VAS score was 2/10 to 3/10 in most of the parturients.

## **OUALITY OF PAIN RELIEF**

After the initial pain relief was achieved parturients were assessed for pain relief using VAS score. In both groups, VAS score was comparable during both stages of labour. Mean VAS score in PCEA group was 2.21 (S.D-0.602) and in CEI group was 2.27 (S.D-0.711) with P value of 0.664.

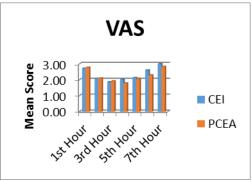


Figure 3: Pain Relief Score.

## MOTOR BLOCKADE

The incidence of motor blockade as assessed using Bromage scale was comparable in both groups. One parturient in PCEA group experienced mild motor blockade (Grade II- assigned a score of 1 out of total 3), which regressed within two hours during labour only.

The mean Bromage score in PCEA group was 0.008 (S.D-0.05) and in CEI group it was 0.000 (S.D-0.000) with P value of 0.322, signifying an insignificant difference.

## MEAN HOURLY DRUG REQUIREMENT

Mean Hourly Requirement was calculated by dividing total drug consumed by the total duration of infusion in hours. The Mean drug requirement in PCEA gr was 10.10 ml/hr (SD=2.78) whereas in CEI gr it was 14.34 ml/hr (SD=2.96). The P value was <0.001 which is significant.

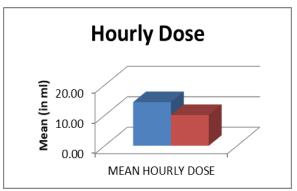


Figure 4: Hourly Drug Requirement.

### DISCUSSION

Childbirth is associated with pain and this sometimes decreases the joy of motherhood. The unprepared and untreated women feel pain due to uterine contractions which are associated with labour progression. The neuraxial analgesia is considered as gold standard for labour analgesia due to its efficacy in quickly relieving pain due to uterine contractions. Studies have established that Epidural Analgesia is suitable for most of the parturients.

Since introduction of Continuous epidural infusion (CEI) of local anaesthetics into common clinical practice in 1980s, a lot of work has been done till date on the labour analgesia using CEI technique, but most of the workers have demonstrated its efficacy in comparison to Intermittent Epidural Bolus techniques. While the technique has circumvented a number of difficulties, it is not ideal. Many patients still required clinician initiated top-ups and experienced unacceptably dense motor block in the lower extremities. Repeated epidural handling increases the risk of infections. Due to higher requirement of drugs there is increased incidence of opioid overdose which may lead to maternal and fetal complications. Although many combinations of infusion rates and various concentrations of local anaesthetics and additives have been used and investigated, these problems persist. Some authors have compared the potencies of different epidurally administered local anaesthetics, opioids and  $\alpha$ 2 agonists.

Patient-controlled epidural analgesia (PCEA) for relief of labour pain was first described by Gambling in 1988. Patient Controlled Analgesia via the epidural route has increased in popularity in last two decades due to its efficacy in providing adequate labour analgesia with less local anaesthetic requirement. The efficacy of PCEA is due to prompt administration of drug and alleviation of anxiety which is often associated with the anticipation of a return of pain.

This technique allowed the patient to control the dose of epidural medication as labour and pain patterns changed. It also allowed for individualization of drug dosage by patient, allowing her to trade off therapeutic effects (e.g. complete pain relief) and side effects (e.g. motor blockade). Thus PCEA has an advantage of less use of local anaesthetics. It also offers an additional benefit of possible reduction in risk of infection, as the frequency for opening the epidural infusion system for additional doses decreases. However, the equipment needed for PCEA may be more expensive than CEI. Also, more time is required to educate both the patient and staff about the appropriate use of the medication and equipment.

Drugs which are most commonly used in Epidural Analgesia are local anaesthetics alone or in combination with opioids or other additives like  $\alpha 2$  agonists etc. Bupivacaine in low dose along with an opioid has been one of the most popular choices. Addition of the opioids allows reduction in dose and concentration of bupivacaine without adversely affecting the quality of analgesia. Reduction in dose of bupivacaine significantly reduces the incidence and severity of motor blockade. Opioid use has its own side-effects like pruritus and occasional neonatal respiratory depression.

This study was chosen to compare two commonly employed Epidural Analgesia techniques (PCEA vs CEI), using Ropivacaine with Fentanyl, in primigravida parturients undergoing labour at a teaching institute. All parturients who requested for pain relief and were fulfilling inclusion criteria were invited to participate in this study.

Findings of our study was consistent with those of previous studies that PCEA provides superior labour analgesia as compared to CEI in terms of decreased requirement of local anaesthetics and lesser intervention by Anaesthesiologist.

# TOTAL DRUG REQUIRED AND MEAN HOURLY REQUIREMENT

The mean hourly requirement of local anaesthetic gives an indication of efficacy of EA technique. In our study results were similar to previous studies in respect to less total drug requirement in PCEA group as compared to CEI group. The mean hourly dose in PCEA group was 10.10 mg/h (S.D-2.78) as compared to 14.34 mg/h in CEI group. This was a significant difference (P<0.001).

This shows that PCEA technique provide analgesia comparable to CEI technique with significantly less dose of local anaesthetic, thus reducing risk associated with higher dose of local anaesthetic.

#### **QUALITY OF PAIN RELIEF**

Quality of pain relief was assessed using visual analogue score. Both PCEA and CEI groups had adequate pain relief with no significant difference in our study.

#### MOTOR BLOCKADE

In our study, there was no significant difference in motor blockade between PCEA and CEI group.

#### CONCLUSION

The following conclusions were drawn from this study:

- 1. Patient controlled epidural analgesia and continuous epidural infusion, both are reliable and effective method of providing labour pain relief.
- 2. Using opioids along with local anaesthetics allow for lower concentrations of local anaesthetics thus reducing incidence of motor blockade.
- PCEA provides similar quality of analgesia as provided by CEI but with lesser requirement of local anaesthetics and opioids.
- 4. Incidence of instrument assisted delivery and surgical intervention was comparable in both the groups.
- 5. There is no significant difference between PCEA and CEI groups in hemodynamic parameters and duration of first and second stages of labour.

## CONFLICTS OF INTEREST

The authors have none to declare.

## **ACKNOWLEDGEMENT**

The authors would like to thank all the subjects who consented to participate in this study.

## REFERENCES

- 1. Breivik H, Borchgrevink PC, Allen SM, et al. Assessment of pain. Br J Anaesth, 2008; 101: 17–24. [PubMed] [Google Scholar]
- 2. Grilo RM, Treves R, Preux PM, et al. Clinically relevant VAS pain score change in patients with acute rheumatic conditions. Joint Bone Spine, 2007; 74: 358–361. [PubMed] [Google Scholar]
- 3. Dworkin RH, Turk DC, Wyrwich KW, et al. Interpreting the clinical importance of treatment outcomes in chronic pain clinical trials: IMMPACT recommendations. J Pain, 2008; 9: 105–121. [PubMed] [Google Scholar]
- Torvaldsen S, Roberts CL, Bell JC, et al. Discontinuation of epidural analgesia late in labour for reducing the adverse delivery outcomes associated with epidural analgesia. Cochrane Database Syst Rev, 2004; 4: CD004457. [PubMed] [Google Scholar]
- 5. Polley LS, Columb MO, Wagner DS, et al. Dosedependent reduction of the minimum local analgesic

- concentration of bupivacaine by sufentanil for epidural analgesia in labor. Anesthesiology, 1998; 89: 626–632. [PubMed] [Google Scholar]
- Ortner CM, Posch M, Roessler B, et al. On the ropivacaine-reducing effect of low-dose sufentanil in intrathecal labor analgesia. Acta Anaesthesiol Scand, 2010; 54: 1000–1006. [PubMed] [Google Scholar]
- 7. Katz JA, Bridenbaugh PO, Knarr DC, et al. Pharmacodynamics and pharmacokinetics of epidural ropivacaine in humans. Anesth Analg, 1990; 70: 16–21. [PubMed] [Google Scholar]
- 8. Lacassie HJ, Habib AS, Lacassie HP, et al. Motor blocking minimum local anesthetic concentrations of bupivacaine, levobupivacaine, and ropivacaine in labor. Reg Anesth Pain Med, 2007; 32: 323–329. [PubMed] [Google Scholar]
- 9. Sultan P, Murphy C, Halpern S, et al. The effect of low concentrations versus high concentrations of local anesthetics for labour analgesia on obstetric and anesthetic outcomes: a meta-analysis. Can J Anaesth, 2013; 60: 840–854. [PubMed] [Google Scholar]
- Haydon ML, Larson D, Reed E, et al. Obstetric outcomes and maternal satisfaction in nulliparous women using patient-controlled epidural analgesia. Am J Obstet Gynecol, 2011; 205: 271 e1–271 e6. [PubMed] [Google Scholar]
- 11. Arendt KW, Segal BS. The association between epidural labor analgesia and maternal fever. Clin Perinato, 2013; 40: 385–398. [PubMed] [Google Scholar]
- 12. Mardirosoff C, Domont L, Boulvain M, et al. Fetal bradycardia due to intrathecal opioids for labour analgesia: a systematic review. BJOG, 2002; 109: 274–281. [PubMed] [Google Scholar]
- 13. Wong CA, Scavone BM, Peaceman AM, et al. The risk of cesarean delivery with neuraxial analgesia given early versus late in labor. N Engl J Med, 2005; 352: 655–665. [PubMed] [Google Scholar]
- 14. Steinberg J. Oxytocin augmentation during labor with epidural analgesia. Am Fam Physician, 2013; 87: 760–761. [PubMed] [Google Scholar]
- 15. OWen MD, D'Angelo R, GeRancheR J C, et al: 0.125% ropivacaine is similar to 0.125% bupivacaine for labor analgesia using patient-controlled epidural infusion. Anesth Analg, 1998; 86: 527-531.
- 16. Campbell DC, ZWack RM, CRone LL, Yip RW: Ambulatory labor epidural analgesia: bupivacaine versus ropivacaine. Anesth Analg, 2000; 90: 1384-9.
- 17. OWen MD, Thomas JA, Smith T, et al: Ropivacaine 0.075% and bupivacaine 0.075% with fentanyl 2μg/mL are equivalent for labor epidural analgesia. Anesth Analg, 2002; 94: 179-83.
- 18. Keld DB, Hein L, DalgaaRd M, et al: The incidence of transient neurologic symptoms (TNS) after spinal anaesthesia in patients undergoing surgery in the supine position. Hyperbaric lidocaine 5% versus hyperbaric bupivacaine 0.5%. Acta Anaesthesiologica Scandinavica, 2000; 44: 285-290.

- 19. ShiFman EM, ButRv AV, Floka SE, Got IB: Transient neurological symptoms in puerperas after epidural analgesia during labor. Anesteziol Reanimatol, 2007; 6: 17-20.
- 20. James RM, Osama BN, David JB, et al: Transient Neurologic Symptoms After Epidural Analgesia. Anesth Analg, 2000; 90: 437.
- 21. TuckeR GT: Pharmacokinetics of local anaesthetics. Br J Anaesth, 1986; 58: 717-731.
- 22. Campbell DC: Labour analgesia: what's new and PCEA too? Can J Anesth, 2003; 50(90001): R8-8.
- 23. Chestnut DH, Bates JN, Choi WW: Continuous infusion epidural analgesia with lidocaine: efficacy and influence during the second stage of labor. Obstet Gynecol, 1987; 69: 323-7.
- 24. NaFisi S: Effects of epidural lidocaine analgesia on labor and delivery: A randomized, prospective, controlled trial. BMC. Anesthesiology, 2006; 6: 15.
- Liu E, Sia A: Rates of caesarean section and instrumental vaginal delivery in nulliparous women after low concentran epidural infusions or opioid analgesia: systematic review. BMJ, 2004; 328(7453): 1410.
- 26. Zhang J, Yancey MK, KlebanoFF MA, SchWaRz J, SchWeitzeR D: Does epidural analgesia prolong labor and increase risk of cesarean delivery? A natural experiment. Am J Obstet Gynecol, 2001; 185: 128-134.