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ORIGINAL ARTICLE

FIRST STAGE OF LABOR: IS IT PROLONGED BY EPIDURAL ANALGESIA IN COMPARISON TO SYSTEMIC ANALGESIA? A PROSPECTIVE CONTROLLED TRIAL

Sam Philip[1], Rakhee S[2], Shaloo Ipe[3], Shalini Miriam Ipe[4], Sara Vergis[5], Saramma P. Abraham[6]

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ABSTRACT: BACKGROUND: Neuraxial labor analgesia might prolong, shorten or not alter the first stage of labor. Prolongation can have deleterious effects on the progress of labor and mode of delivery which can be undesirable for the parturient and neonate. No randomized controlled trial has investigated the duration of first stage of labor as a primary outcome, with epidural analgesia compared to systemic analgesia. Methods: 500American Society of Anesthesiologists (ASA) physical status I primigravidae, aged 18-35 years, gestational age>37 weeks with singleton cephalic presentation were divided into study (epidural) and control (systemic analgesia) groups. The systemic group received tramadol 2mg/kg and phenergan 0.5mg/kg intramuscularly sixth hourly. The study group received 10ml 0.1% Ropivacaine with 50mcg Fentanyl bolus. 0.1% Ropivacaine with Fentanyl 0.0001% was given as infusion at 5ml/hr. For break through pain and at full cervical dilatation, 5ml bolus of the drug was given. The first stage was from active phase of labor to full cervical dilatation (10cm). Maternal& neonatal outcome and analgesia were monitored. Results: 203 parturients in the study group and 208 in the control group completed the study. First stage was significantly prolonged in the study group compared to the control group (367.39±76.72min v/s 308.22±89.31min, p value=0.000, 95% CI= (-75.33, -43.00)). The safety of mother and neonate was ensured. Quality of analgesia was excellent or good in 70% of the parturients in study group and 25% in the control group. Conclusion: Epidural analgesia compared to systemic analgesia, prolongs the first stage of labor, but is not associated with adverse maternal or neonatal outcome.
KEYWORDS: Epidural, Systemic analgesia, Ropivacaine, Fentanyl, Tramadol.

INTRODUCTION: It is believed that epidural analgesia prolongs the duration of first stage of labor. There is no randomized controlled trial investigating this as a primary outcome. Studies that assessed duration of first stage as a secondary outcome reported that it was unaltered in some[1,5] while it was prolonged in some[6] and shortened in some others.[7,8,9] This was a prospective controlled trial assessing the duration of first stage of labor in epidural analgesia in comparison to systemic analgesia as a primary outcome. Quality of analgesia and maternal and neonatal safety were considered.

METHODS: A prospective study was conducted with the approval of the hospital Ethics Committee. 500 parturients in labor were enrolled in the study after signing written informed consent. Power of study was calculated using NESS and PASS.

Considering duration of first stage of labor as primary outcome, based on a pilot study with matched controls, with an alpha error of 5% and power of study 90%, the number of cases required was 200 in each group. To allow for a drop out of 20%, we increased the sample size to 250per group.

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The inclusion criteria were American Society of Anesthesiologists (ASA) physical status I, nulliparity, age 18-35 years, gestational age >37 weeks, single fetus with vertex presentation. Exclusion criteria included infection at the site of epidural, coagulopathies, any spinal deformities, history of allergy to local anesthetics, fentanyl or tramadol.

All parturients were counseled on admission to the labor ward and those who were desirous of epidural analgesia were allocated to the epidural group (study group) and those opting for systemic analgesia, to the control group. Visual Analogue Pain Scale (VAPS) was used for quantification of pain at the peak of uterine contractions (0mm = no pain and 100mm = worst pain).

Motor block in the lower extremities were assessed using modified Bromage score (0=no block, 1=unable to raise extended leg, able to move knees and foot, 2=unable to raise extended leg or knees, able to move foot, 3=complete motor block of the lower limbs), ECG, SpO_2 and NIBP were monitored using multichannel monitors (Philips Intellivue MP20) with trend facilities.

Hypotension was defined as a systolic blood pressure less than 100mm Hg or 80% of the baseline values and bradycardia as heart rate less than 60/min. Oxygen saturation below 94% in room air was considered abnormal and oxygen was supplemented. Hypotension was managed by rapid infusion of lactated Ringer's solution and, or intravenous boluses of ephedrine 6mg and bradycardia by intravenous glycopyrollate.

Ondansetron 4mg was given intravenously at 8 hourly intervals. Cervical dilatation and VAPS score at the time of initiation of analgesia was noted. Duration of first stage of labor was taken as the interval between the beginnings of active phase of labor (regular contractions with 3-4 cm dilatation) to full cervical dilatation (10cm).

Subjective score of parturient satisfaction for analgesia was obtained on a five point scale (4=excellent, 3=good, 2=fair, and 1=poor, 0=unequivocal). Any maternal complications such as fever, dizziness, headache, back pain, nausea, vomiting, itching, post-partum hemorrhage and urinary retention were recorded. Management of labor was as follows. Oxytocin was administered in titrated doses to augment labor till regular contractions occurred at every 2-3 minutes interval.

Vaginal examinations were conducted every two hours, at the time of parturient experiencing the urge to strain and whenever it was indicated as decided by the obstetrician. Continuous tococardiography monitoring evaluated uterine contractions and fetal heart rate.

Systemic or epidural analgesia was initiated when there were regular contractions at 5 minute intervals associated with progressive cervical effacement and dilatation of 3–4cm. Parturients were preloaded with 500ml of lactated Ringer's solution over a period of 30 minutes and thereafter fluid infusion was maintained at the rate of 2-3ml/kg per hour.

As per the usual labor room protocol, the systemic analgesia group received tramadol 2mg/kg and phenergan 0.5mg/kg intramuscularly at 6 hourly intervals, the last dose being at 6cm dilatation.
In the epidural group, in lateral position, an epidural catheter was inserted at L2-3 or L3-4 intervertebral space using loss of resistance to air technique and fixed at 2 to 3cm in the epidural space. Epidural test dose was omitted for the purpose of study.

After confirming negative aspiration for blood and CSF, analgesia was initiated with 10ml bolus of 0.1% ropivacaine with 50mcg fentanyl. We used continuous epidural infusions because that was the standard technique practiced in our institution. 0.1% ropivacaine with fentanyl 0.0001% was instituted as an infusion at 5ml per hour using a syringe pump (B Braun) after half hour of initial bolus dose.

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Boluses of 5ml of the drug were given for break through pain and for perineal analgesia in the second stage of labor. Parturients were nursed in supine position maintaining a 15° lateral tilt alternating between right and left side. ECG, NIBP, pulse rate and oxygen saturation were monitored continuously. Motor block and VAPS score at the peak of uterine contractions were recorded every 30 minutes.

STATISTICAL ANALYSIS: Data analysis was done using IBM Statistical Package for Social Sciences (SPSS) version 22. Summary of the continuous variables were presented as mean+standard deviation. A p-value of <0.05 was considered as statistically significant. Analysis of variables of interest was compared among the groups using independent sample t-test.

RESULTS: Parturient recruitment and data collection occurred over a period of two consecutive years. Out of the 500 parturients who participated, 411(208 in the systemic group and 203 in the epidural group) completed the study. 47 patients from the epidural group were excluded as epidural analgesia was ineffective in 3 cases, data was incomplete in 4cases and in 40 cases caesarean was done before full cervical dilatation. Similarly 42 in the systemic group were excluded as the data was incomplete in 9 and in 33 cases caesarean was done before full cervical dilatation.

	Systemic group (n = 208)	**Epidural group (n = 203)**	**p-value**
Age (yrs)	25.04±2.95	24.49±2.78	0.070
Weight (kgs)	63.11±8.21	62.58±6.79	0.482
Height (cm)	156.82±7.10	157.78±6.96	0.161
Gestation (wks)	38.58±1.18	38.57±1.17	0.901
Cervical dilatation at epidural (cm)	3.69±0.72	3.76±0.71	0.374
Baseline VAPS	48.70±11.58	48.28±11.67	0.765

Table 1: Parturient characteristics(Mean ± SD)

Demographic details and parturient observations were similar at the time of initiation of analgesia (Table 1).

DURATION OF FIRST STAGE: The mean duration of first stage was significantly prolonged in the epidural group compared to the systemic analgesia group (367.39±76.72min v/s 308.22±89.31min, p value=0.000, 95 % CI=(-75.33, -43.00)).

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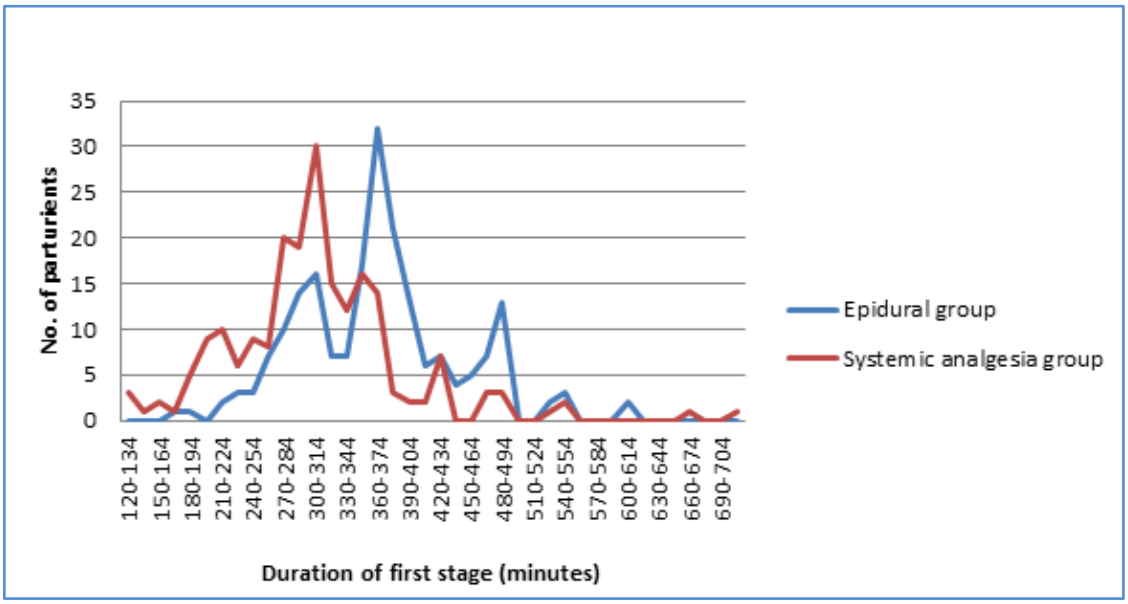

Fig. 1: Duration of first stage

Maximum number (near 15%) in the systemic group and (near 15%) in the epidural group reached full cervical dilatation at 300-314 minutes and 360-374 minutes respectively (difference-60 minutes). At 300-314 minutes, when maximum number (15%) of parturients reached full cervical dilatation in the systemic group, only 7.9% reached full cervical dilatation in epidural group.

NEONATAL OUTCOME: Mean APGAR scores at 1 minute and 5 minutes were comparable between the two groups. All neonates had an APGAR score of 9 or 10 at 5 minutes. Umbilical venous blood gas values were within normal limits (Table 2). Three in the study group and two in the control group needed observation in the ICU for 24 hours.

Neonatal outcome		Systemic gp. (n = 208)	Epidural gp. (n = 203)	p-value
Apgar scores	1 min	8.50±0.86	8.41±0.95	0.306
	5 min	9.88±0.32	9.91±0.29	0.490
Umbilical venous blood gas	pH	7.35±0.02	7.35±0.03	0.171
	pO2(mmHg)	26.05±2.49	25.76±2.26	0.187
	pCO2(mmHg)	39.25±3.23	39.02±3.29	0.525
	HCO3(mmol/L)	19.76±0.96	19.97±1.66	0.105
	BE	-5.76±0.92	-5.90±0.94	0.154

Table 2: Neonatal outcome

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Maternal effects	Systemic gp. (n = 208)	Epidural gp. (n = 203)	p-value
PPH	1	0	0.311
Nausea/Vomiting	4	4	0.972
Pruritus	3	11	0.033
Numbness	0	3	0.086
Shivering	7	6	0.744
Headache	4	3	0.679
Back pain	9	12	0.539
Fever ≥100°	2	4	0.492

Table 3: Maternal adverse effects

There was no hypotension, bradycardia, hypoxia or urinary retention in any of the parturients in either group. Post-partum hemorrhage (PPH), nausea, vomiting, numbness, shivering, headache and back pain which occurred in small numbers were distributed equally between the groups. Incidence of pruritus was significantly higher in the epidural group (Table 3).

QUALITY OF ANALGESIA: Quality of analgesia was excellent or good in 70% of parturients in epidural group and only 25% in systemic analgesia group. Analgesia was poor in 25% of parturients in systemic analgesia group (Fig.2).

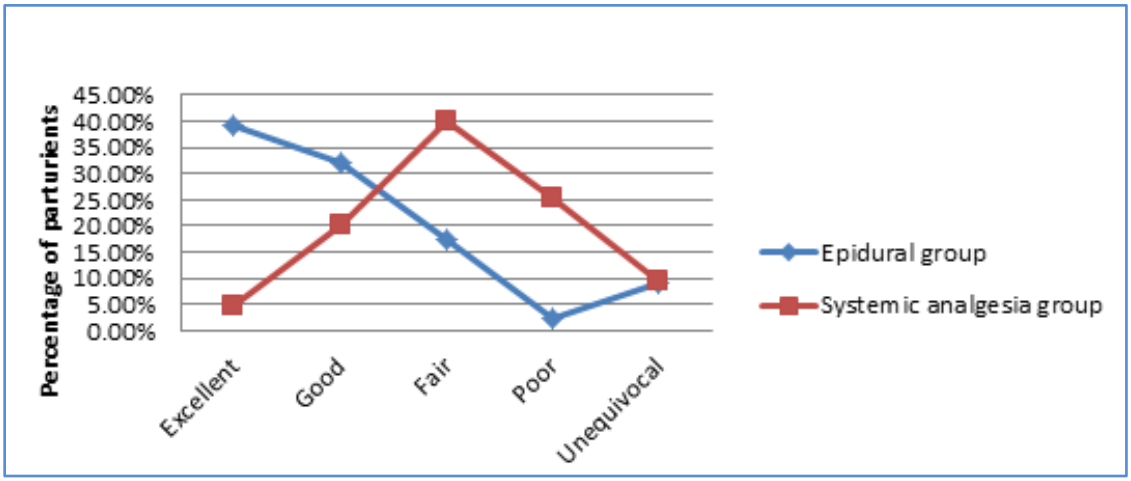

Fig. 2: Quality of analgesia

DISCUSSION: Labor induces considerable pain and hence warrants analgesia. The age old practice of pain relief in labor is by systemic medication. Systemic medication is easier to administer and is less invasive.

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However, the rising concerns of inadequate analgesia, maternal and neonatal side effects has led to the quest for a better techniques of analgesia like neuraxial (epidural) analgesia which is now regarded as the gold standard for pain relief during labor.

It is commonly assumed that parturients who are given neuraxial labor analgesia have longer duration and poor progression of labor and those they may end up having more instrumental vaginal deliveries. Prolonged labor can be undesirable for the mother and the fetus.

The possible concerns of prolonged labor include the need for prolonged analgesia, increased incidence of chorioamnionitis, neonatal and puerperal sepsis. These fears are a stumbling block in recommending epidural labor analgesia by the obstetricians. The parturients are also very often reluctant to request for it because of these reasons.

In the present study, the duration of first stage of labor was significantly prolonged in the epidural group by 59 minutes. (367.39±76.72min v/s 308.22±89.31min, p value = 0.000, 95% CI = (-75.33, -43.00)). Maximum number (near 15%), reached full cervical dilatation at 300-314 minutes in systemic group and 360-374 minutes in epidural group (difference-60 minutes).

At 300-314 minutes, when maximum number (15%) of parturients reached full cervical dilatation in the systemic group, only 7.9% reached full cervical dilatation in epidural group. The available evidence suggests that neuraxial labor analgesia has a variable effect on the duration of the first stage of labor. Our results are in consensus with that of Behrens &colleagues,[10] and Rahm & colleagues[11] who demonstrated decreased uterine activity with epidural analgesia due to reduction in prostaglandin F2 alpha and oxytocin release resulting in prolonged labor.

These conflicting reports may be a result of varied factors which affect the contraction of uterus and thus the first stage of labor. An attempt was made to standardize the factors which influence uterine contraction and hence affect the first stage of labor.

Oxytocin infusion was used in 65% of patients in the control group against 67% patients in the epidural group in titrated doses to augment labor so that regular contractions occurred at 2-3 minutes interval. In this study, parturients were preloaded with 500ml of lactated Ringer's solution over a period of 30 minutes and thereafter fluid infusion was maintained at the rate of 2-3ml/kg per hour.

One liter of crystalloid solution, but not 0.5 liter is demonstrated to decrease uterine activity due to the release of antidiuretic hormone which temporarily decreases the production of oxytocin as both hormones are released by the posterior pituitary gland.[12,13] In contrast, there are studies which demonstrate augmentation of uterine activity and reduction in the duration of labor due to decreased plasma epinephrine and sympatholysis with epidural analgesia.[14,-17]

Neonatal status at birth was similar and acceptable in both the groups. The prolongation of first stage of labor in the epidural group did not affect the neonatal outcome. Prolongation of labor demands prolonged analgesia. Prolonged epidural analgesia per se is unlikely to cause respiratory depression in the same proportion as systemic analgesia with opioids.

Analgesia offered by neuraxial blockade is of a much superior quality. In the doses commonly used for labor, systemic medication is much less effective than epidural for pain relief. Because of the possibility of respiratory depression, administration of systemic analgesia is restricted in late labor.

This can result in inadequate analgesia, and also there can be respiratory distress in the newborn if multiple and relatively large doses are given within few hours before delivery or if the labor progresses much more quickly than expected.

Maternal adverse effects were minimal and equal in both the groups. Incidence of pruritus, though mild in nature was higher in the epidural group most likely due to fentanyl added to the local anesthetic.

Epidural analgesia prolonged the first stage of labor without any adverse effects in the parturient and neonate while providing superior analgesia.

CONCLUSION: Epidural analgesia compared to systemic analgesia, prolongs the first stage of labor, but is not associated with adverse maternal or neonatal outcome.

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AUTHORS:

1. Sam Philip
2. Rakhee S.
3. Shaloo Ipe
4. Shalini Miriam Ipe
5. Sara Vergis
6. Saramma P Abraham

PARTICULARS OF CONTRIBUTORS:

1. Associate Professor, Department of Anesthesiology, MOSC Medical College Hospital, Kolenchery, Ernakulam, Kerala.
2. Assistant Professor, Department of Anesthesiology, MOSC Medical College Hospital, Kolenchery, Ernakulam, Kerala.
3. Professor, Department of Anesthesiology, MOSC Medical College Hospital, Kolenchery, Ernakulam, Kerala.
4. PG Trainee, Department of Anesthesiology, MOSC Medical College Hospital, Kolenchery, Ernakulam, Kerala.
5. Associate Professor, Department of Anesthesiology, MOSC Medical College Hospital, Kolenchery, Ernakulam, Kerala.
6. Professor & HOD, Department of Anesthesiology, MOSC Medical College Hospital, Kolenchery, Ernakulam, Kerala.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Sam Philip,
Associate Professor,
Department of Anesthesiology,
MOSC Medical College Hospital,
Kolenchery, Ernakulam,
Kerala-682311.
Email: drsam_p@hotmail.com

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