ORIGINAL ARTICLE

A CLINICAL COMPARATIVE STUDY OF INTRAPARTUM EPIDURAL ANALGESIA WITH INTRAMUSCULAR TRAMADOL WITH RESPECT TO MATERNAL AND PERINATAL OUTCOME

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ABSTRACT: BACKGROUND AND OBJECTIVES: Labor pain is among the severest pains experienced by women. The need for analgesia to overcome pain in labor is highly requested by women today, being the best if facilities are available. But in developing nations IM opioids can be considered. The objective of the study is to compare the effects of intrapartum epidural analgesia with IM Tramadol on progress of labor, maternal and fetal outcome and level of pain relief. **METHODS:** 120 low-risk Primigravidae attending labor room at IMCH attached to Govt Medical College, Kozhikode during the period of one and half year, from February 2012 to August 2013. Primigravidae were randomly divided into two groups. Group I (60) Administered epidural analgesia at 3-4cm of cervical dilatation. Group II (60) Administered IM Tramadol 100mg at 3-4cm of cervical dilatation. Main outcome measures studied: 1. Duration of active phase of I stage, II stage and III stage. 2. Mode of delivery. 3. APGAR scores. 4. Untoward reactions and intrapartum complications. 5. Overall satisfaction of the mother. **RESULTS:** Epidural analgesia has shortened the duration of I stage of labour by 45.5min and total duration of labor (by 34min). It has given excellent pain relief and improved neonatal outcome (5min) compared to IM Tramadol. EA is not associated with instrumental vaginal delivery (14% v/s 16%) and LSCS rate (2% v/s 6%). **CONCLUSION:** EA in labor is highly effective and safe for both mother and the fetus. It has favourable effect on progress of labor, pain relief and neonatal outcome when compared to IM Tramadol. But with limited facilities IM Tramadol can be considered as suitable alternative.

KEYWORDS: Intrapartum Epidural Analgesia, Intramuscular Tramadol, Maternal outcome, Perinatal Outcome.

INTRODUCTION: Labor pain ranks among the severest forms of pain, having been described as 'intolerable' by a third of women. Labor is a complex mixture of biological mechanisms with mixed emotions and pain. The ability to produce pain relief is desirable enough in its own right.[1] Rick ford and Regnolds suggest that it is not that women underestimate the pain, but tend to overestimate their ability to cope with it.[2]

The need for analgesia to overcome pain in labor is requested highly by women today. Various ways either non-pharmacologic e.g. emotional sustain, psycho prophylaxis, Acupuncture, Abdominal decompression, yoga and hypnosis or pharmacologic like systemic opioids, regional nerve blockade, etc. are used.[3]

Lumbar epidural analgesia has potential to be such a technique. It achieves analgesia in labor without clouding of consciousness, allowing the mother to be fully alert throughout labour.[4]

Out of all the analgesic methods tried ACOG suggests that "Epidural block is the most effective and least depressant (pharmacologic option) allowing for an alert mother."[5]

Studies suggested that providing pain relief has positive impact on both mother and fetus and their outcome.[6] An ideal analgesic is the one that can provide pain relief throughout the entire labor process with no side effects on both mother and fetus and should be cheap, easy to administer, should not impair consciousness/cooperation. It should be non-toxic to mother and fetus, and not produce cardiorespiratory depression in the fetus.

The technique must have no tocolytic action and not delay labour.[7] Since India has poor resource setting, if facilities for epidural blockade is not available or feasible or if epidural blockade is contraindicated, we should consider providing parenteral opiods like IM Tramadol, which is still a very good option.[8] Various studies done so far have given contradictory results with respect to epidural analgesia and its labor outcome. In short this study is to compare and analyze the effect of intrapartum epidural analgesia with IM tramadol, with respect to maternal & fetal outcome.

METHODOLOGY: This study was conducted on patients who are primigravida with low risk pregnancy attending labor ward at IMCH attached to Govt. Medical College, Kozhikode during the period of one and half year, from February 2012 to August 2013.

INCLUSION CRITERIA:

1. Primigravida.
2. Age group between 18 and 30 years.
3. Height above 145 cm.
4. Single live fetus with term gestation with vertex presentation.
5. Spontaneous onset of labor.
6. Women in active phase (that is 3-4 cm cervical dilatation) with good uterine contractions.

All other pregnancies were excluded from the study.

METHOD OF COLLECTION OF DATA: Primigravida were randomly divided into two groups.

Group I – Women administered epidural analgesia at 3-4 cm of cervical dilatation.

Group II – Women administered IM tramadol 100 mg at 3-4 cm of cervical dilatation.

Group I mothers were given lumbar epidural analgesia using 0.125% bupivacaine (10 cc) + 20 mcg of fentanyl (1cc) using loading and intermittent bolus by the anaesthesiologist.

Group II mothers were given Inj. Tramadol 100 mg IM and repeated after 4 hours if required.

THESE TWO GROUPS WERE COMPARED UNDER FOLLOWING CHARACTERISTICS:

1. Duration of labor (active phase of I stage, II stage, total duration of labor).
2. Mode of delivery & amount of blood loss.
3. APGAR score of new born (1 min and 5 min).

4. Untoward reaction and intrapartum complications.
5. Overall satisfaction of the mother.
6. Pain relief using visual analogue scale.

PRE-REQUISITES:

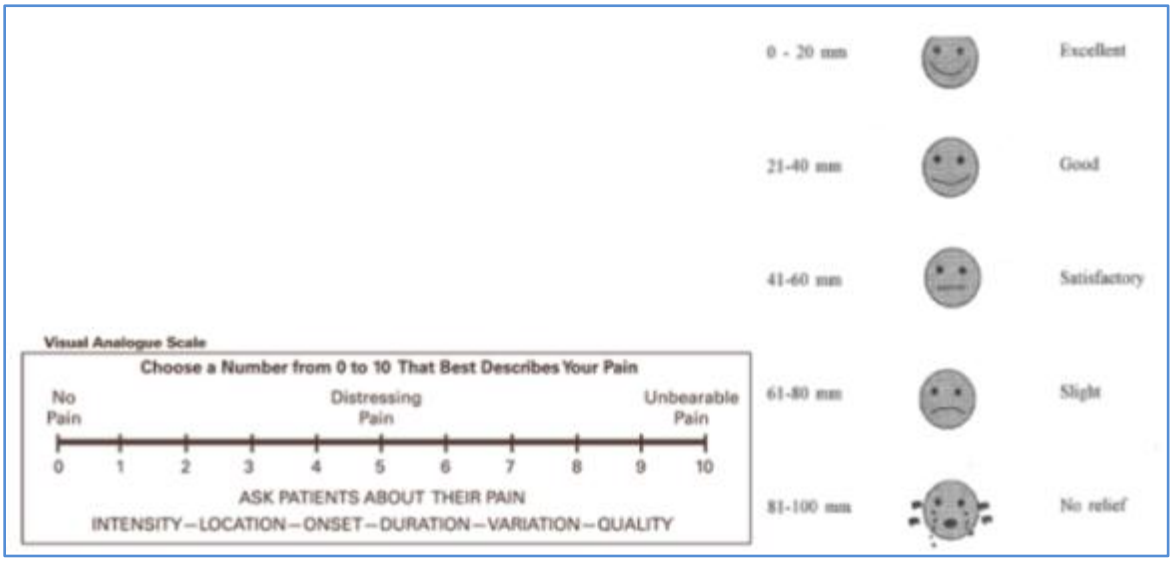
- Informed written consent from study group patients.
- Continuous monitoring of the haemodynamic parameters (pulse rate, blood pressure, ECG and O2 saturation) of the mother using multi parameter monitors.
- Fetal monitoring using continuous CTG.
- Anaesthesia machine with all resuscitative equipment and emergency drugs.

EQUIPMENT'S

- An epidural set with 16 G Huber point Tuohy needle, epidural catheter.
- Bupivacaine and fentanyl.
- A 24 G needle and 5 ml syringe for local anaesthetic infiltration.
- A 10 ml dry glass syringe.
- Delivery tray.
- Baby resuscitation tray.

TECHNIQUE OF EPIDURAL ANALGESIA: Using ideal techniques precautionary measures and using a 16G Touhy needle into L2-3 or L3-4 space, 0.125% Bupivacaine with 20mcg fentanyl was given as loading dose. Patient was monitored for vital signs and side-effects of epidural analgesia every 15mins.The progress of labor was plotted on a partogram.

TOOLS COMMONLY USED TO RATE PAIN:



STATISTICAL METHODS APPLIED:

- Frequencies and percentages.
- Chi-square test.
- Crosstabs.
- Statistical analyses were carried out using SPSS for Windows (Version 16.0)

RESULTS:

- Duration of I stage of labor.
- Duration of first stage of labor was calculated taking into account only from active phase of labor.
- In group I it ranged from 90 min to 300 min.
- In group II it ranged from 105 min to 305 min.
- Duration of I stage is shortened by 45.5 min when compared to group II, which is statistically significant ($p < 0.001$).

Duration range (min)	Group I		Group II	
	No.	%	No.	%
90-150	21	42	7	14
151-210	24	48	19	38
211-310	5	10	24	48

The mean duration of I stage in the group I was 166.1, 46.47 min and 211.6, 52.16 min in the group II. This confirms that epidural analgesia does not prolong the 1st stage of labor in fact it may shorten the I stage of labor by reducing maternal anxiety. Forty-five patients (90%) in group I were fully dilated within 3½ hours (210 min) of commencement of epidural analgesia, whereas only 26 patients (52%) in the group II were fully dilated at the end of 4 hours.

DURATION OF II STAGE:

- The duration of II stage of labor ranged from 10-85 min in group I
- The duration of II stage of labor ranged from 15-90 min in group II
- The mean duration of II stage in group I (38.91 & 20.18 min) is shorter than group II (40 19.57 min) but statistically not significant ($p = 0.670$).

Duration range (min)	Group I		Group II	
	No.	%	No.	%
< 30	22	44.9	17	36.1
31-60	21	42.9	24	51.1
61-90	6	12.2	6	12.8
Total	49	100	47	100

DURATION OF III STAGE OF LABOUR:

III stage	Group I	Group II
Duration of III stage	3-10 min	2-20 min
Mean ± SD	7.2 min	7.1 min

Duration of III stage of labour range from 3 to 10 min (mean 7.2 min) in the group I and 2 min to 20 min (mean 7.1 min) in the group II. Duration of III stage not significantly affected by epidural analgesia.

TOTAL DURATION OF LABOUR: Total duration of labour is significantly shortened in group I when compared to group II by 47.44 min.

	Group I	Group II
Total duration of labour	108-370 min	122-415 min
Mean	214.42 ± 55.40	261.87 ± 61.38

It is shortened by 34 min in group I, which is statistically significant ($p<0.001$).

MODE OF DELIVERY:

Mode of delivery	Group I		Group II	
	No.	%	No.	%
Spontaneous vaginal delivery	42	84	39	78
Ventouse	5	10	4	8
Outlet forceps	2	4	4	8
LSCS	1	2	3	6
Total	50	100	50	100

In group I, 42 patients (84%) had vaginal delivery, 5 patients (10%) had ventouse assisted delivery, 2 patients (4%) had outlet forceps delivery and 1 patient underwent LSCS. In group II, 39 patients (78%) had vaginal delivery, 4 patients (8%) had ventouse assisted delivery, 4 patients (8%) had outlet-forceps assisted delivery and 3 patients underwent LSCS.

So there is no significant difference in the rate of instrumental deliveries in both study and group II, and in fact the number of LSCS is more in group II when compared to group I. So there is no significant increase in the rate of instrumental deliveries and LSCS in epidural analgesia group. Total number of assisted delivery (both instrumental and LSCS) are 19/100.

ASSESSMENT OF PAIN RELIEF (BY VAS) VISUAL ANALOGUE RELIEF

VAS	Group I		Group II	
	No.	%	No.	%
0-20	40	80	0	0
21-40	9	18	4	8
41-60	1	2	12	24
61-80	0	0	26	52
81-100	0	0	8	16

Pain relief was excellent (80%) in group I, whereas it is slight (52%) to satisfactory (24%) in group II. No patient in group II had excellent pain relief. Pain relief is statistically significant in group I ($p<0.000$) when compared to group II.

NEONATAL OUTCOME: APGAR score in the group I was 6.72, 1.12 and 8.78, 0.76 at 1 min and 5 min respectively. In control it was 6.32, 1.20 and 8.4, 0.8 at 1 min and 5 min respectively. APGAR scores are statistically significant in group I ($p=0.018$) at 5 min.

	1 min	5 min
Group I	6.72 ± 1.12	8.78 ± 0.76
Group II	6.32 ± 1.20	8.4 ± 0.8

COMPLICATIONS:

Complications	Group I		Group II	
	No.	%	No.	%
Nil	30	60	42	84
Vomiting	2	4	2	4
Urinary retention	4	8	0	0
Rigor	4	8	0	0
Motor block (Bromage I)	5	10	0	0
Hypotension	1	2	0	0
Sedation	4	8	2	4
Dry mouth	0	0	4	8

There were two major complications (hypotension and motor blockade) among group I which were managed by appropriate measures. Rest of the complications was minor. Number of complications are more in the group I when compared to group II which is statistically significant ($p<0.001$).

OVERALL MATERNAL SATISFACTION:

Maternal satisfaction	Group I		Group II	
	No.	%	No.	%
Excellent (E)	40	80	0	0
Good (G)	9	18	4	8
Satisfactory (ST)	1	2	12	24
Slight (SL)	0	0	26	52
No (N)	0	0	8	16

Overall maternal satisfaction was excellent in the group I when compared to group II where majority patients had only slight pain relief, which is statistically significant ($p<0.000$).

DISCUSSION: Intra partum epidural analgesia provides effective pain relief in labor and vaginal delivery while the mother remains alert and cooperative during labor. A combination of epidural opioids with local anesthetics has been used in various studies to improve pain relief during labor and to reduce the side effect such as motor paralysis of abdomen and pelvic muscles usually seen when local anaesthetics are used alone.

In our study we used 0.125% bupivacaine and 20 g of fentanyl. The initial bolus dose was 10 ml of 0.125% bupivacaine + 20 g fentanyl. Each to pup dose contained similar dose of bupivacaine + fentanyl, and for group II 100 mg IM Tramadol and same dose repeated after 4 hours if necessary. The patients in groups I and II belong to the age group of 18-28 years.

All patients were in active phase of labor with cervical dilatation >3 cm. Labor was augmented by artificial rupture of membrane oxytocin drip, as per individual needs. The protocol of active management of labor was adopted. Uterine contractions were normal and effective in both groups I and II.

QUALITY OF PAIN RELIEF: Pain relief was excellent in 80% of patients of group I, whereas it was slight to satisfactory in majority of group II. Episiotomy pain relief was good in 37 patients and 11 patients required local infiltration as the last top up dose – delivery interval exceeded 90 min. Whereas, all patients in the group II required local infiltration for pain relief.

COMPARATIVE STUDY OF DURATION OF I STAGE OF LABOR (GROUP I)

- Duration of I stage of labour in Group I of our study is 166.1 & 46.47 min.
- In Impey L et al.[9] (2000) study the duration of I stage is 294 & 156.
- So duration of I stage of labour is significantly shortened in our study.

COMPARATIVE STUDY OF DURATION OF I STAGE OF LABOUR (GROUP II)

- In our study, the duration of I stage of labour in Group II is 211.6 & 52.16 min.

- In Thakur Rathna, Patidar Rekha (2004) study duration of I stage of labour is 266 & 112 min which is prolonged compared to our study.
- In Meena Jyothi et al. (2006) study with programmed labour duration of I stage of labour is significantly shortened.
- Finally, compared to i.m. group II, the mean duration of I stage labour is significantly shortened in group I ($p<0.001$).

COMPARATIVE STUDY OF DURATION OF II STAGE OF LABOUR: Duration of II stage is not significantly prolonged in the group I of present study compared to study conducted by Impey L et al., MacQillan K, Rockson, Joe A (2000).[9] Duration of II stage in intramuscular group II of our study is prolonged compared to Meena Jyothi (2006) study of programmed labour and Thakur Rathna, Patidar Rekha (2004) comparative study of TENS and Tramadol hydrochloride for pain relief in labour. Between group I and group II of our study. Duration of II stage is not significantly prolonged. This shows that epidural analgesia with low dose of bupivacaine and fentanyl does not cause motor blockade and does not interfere with the descent or internal rotation of the presenting part or maternal expulsive forces.

DURATION OF III STAGE OF LABOUR: Mean duration of III stage of labour in the present group I was 7.2 min and 7.1 min in group II. This confirms that epidural analgesia does not affect III stage of labour. This is further supported by the fact that there were no III stage complications in the group I like postpartum hemorrhage or retained placenta. Epidural analgesia has a favorable outcome in the control of PPH by causing uterine retraction by its sympathetic blockade.

TOTAL DURATION OF LABOUR: In group I, mean total duration of labour is significantly shortened as compared to mean total duration of labour in Impey L et al. (2000) study and it is 333 & 176 min.

In group II, total duration of labour is shortened (261 & 61.38 min) as compared to study by Thakur Rathna et al. (2004) where the total duration of labour is 283.45 & 168.5 min. But it is significantly larger compared to study by Meena Jyothi et al. (2006) (187.4 & 61.49 min) because of programmed labour. In the present study, total duration of labour is shortened by 47 min in group I compared to group II, which is statistically significant ($p<0.001$). This is in accordance with the study by Rogers R et al. (1999).

From the above observation it is inferred that the duration of I stage is shortened by allaying maternal anxiety and enabling augmented cervical dilatation.

MODE OF DELIVERY:

- 42 (84%) patients in group I v/s 39 (78%) patients in the group II had spontaneous vaginal delivery.
- 5 (10%) patients in group I v/s 4 patients (8%) in group II delivered by ventouse.
- 2 (4%) patients in group I v/s 4 patients (8%) in group II delivered by forceps.
- Total 7 patients in group I v/s 8 patients in group II delivered by instrumental delivery.

- This shows that there is no statistically significant increase in the rate of instrumental delivery in group I compared to i.m. group II as compared to James KS et al. (1998) study.[10]
- 98% patients delivered vaginally compared in group I to 94% patients in group II.
- LSCS rate was 2% in group I compared to group II it was 6%.
- Epidural analgesia has not significantly increase the caesarean delivery rate as compared to Zun Zhang et al. (2001) (14.4%).[11] In fact it has reduced the rate of caesarean section.

One patient in the group I underwent LSCS. Indication was fetal distress due to thick meconium stained liquor. Whereas 3 patients in group II underwent LSCS. Indications were fetal distress (1), persistent OP position (1) and secondary arrest of descent and dilatation (1). Last two indications were due to malposition. With this observation, epidural analgesia does not increase the rate of LSCS; in contrast it reduces the risk in nulliparous.

APGAR score 1 min APGAR scores of the present study is less compared to study by Nagaria Tripti et al. (2006) and Jaitley Anu et al. (2011).[12] Between group I and group II, APGAR scores of the newborn, 5 min APGAR more in group I, which was statistically significant. This shows that epidural analgesia improves neonatal outcome compared to IM opioids which may cause respiratory depression in the newborn.

PAIN RELIEF: In group I of present study, pain relief is almost same as compared to Jain et al. (2003). 80% of patients had excellent pain relief. In group II of present study, pain relief is less as compared to Thakur Rathna et al. (2004) study. Majority of the patients had only slight pain relief. Between groups I and II, group I of patients had statistically significant pain relief which cannot be compared to IM tramadol.

COMPLICATIONS: Majority of patients in the present study group I had no side effects. Only 1 patient had hypotension SBP < 100 mmHg, which was managed by IV fluids. Other side effects are minor. Complications in group II were minor and comparable to Thakur Rathna et al. (2004) study.

CONCLUSION: EA in labor is highly effective and safe for both mother and the fetus. It has favourable effect on progress of labor, pain relief and neonatal outcome when compared to IM Tramadol. But with limited facilities IM Tramadol can be considered as suitable alternative.

BIBLIOGRAPHY:

1. Rudra A. Issue 18 (2004); Article 3: 1 of 2 update in Anaesthesia.
2. Reynolds RWJK. Expectations and experiences of pain relief in labour. The Society for Obstetric Anaesthesiology and Perinatology (Abstracts). Halifaa: Nova Scotia; 1987. p. 163.
3. Fieni S, Ageri C, Kaihura CT. Perinatal effects of two analgesics, tramadol chlorhydrate and meperidine chlorhydrate, when used during labour. Acta Biomedical de Patenco Parmensa Supplement 2000; 71: 397-400.

4. Arulkumaran SS, Rathnam SS, Bhaskar Rao K. Management of labour. 2nd ed. Chapter 3. Orient Longman Publication; pp. 53-6.
5. Bofill JA, Vincent R D, Ross E L. Nullipoarous active labour, epidural analgesia and cesarean delivery for dystocia. Am J Obstet Gynecol 1997: 177: 1465-70.
6. Viegar OAC, Benny Khaw, Ratnam SS. Tramadol in labour pain in primiparous patients – A prospective comparative clinical trial. EJ Obst & Gynec & Repord Biology 1993; 49: 131-5.
7. Tham Suct Lan Lee, Tat Leang. Pain relief in labour. In: The management of labour, Arulkumaran SS, Rathnam SS, Bhaskar Rao K, eds. 2nd ed. Orient Longman Publication; pp. 53-6.
8. Jain S, Agra V, Gopala S, Jain V. Analgesic efficacy of i.m. opioids versus epidural analgesia in labour. Indian Journal of Obstet & Gynecol 2003; 83 (1):19-27. 44.
9. Impey L, MacQillan K, Rockson M. Epidural analgesia need not increase operative delivery rates. American Journal of Obstetrics & Gynaecology 2000 Feb; 182 (2): 358-63.
10. James KS, MacGrady E, Quasim I. Comparison of epidural bolus administration of 0.25% bupivacaine and 0.1% bupivacaine with 0.0002% fentanyl for analgesia during labour. British Journal of Anaesthesia 1998 Oct; 81 (4): 507-10.
11. Zun Zhang. Does epidural analgesia prolonged labour and increased risk of cesarean section? AJOG 2001 Jul; 185 (1): 128-34.
12. Fung BK. Epidural analgesia for painless labour does not increase the incidence of caesarean. Acta Anaesthesiol-Sin 2000 Jun; 38: 79-84.
13. Jaitley A, Singh S, Srivastava Uma, Nigarath Arun, Prajapati NC, Singh Richa. A comparison between epidural and IV tramadol for painless labour and effect on perinatal outcome. IJOG 2011 Jan/Feb; 42-7.

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