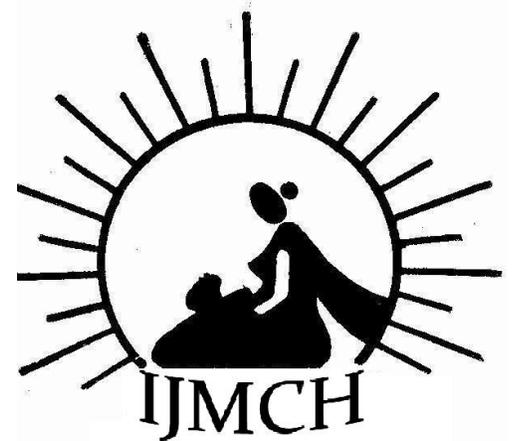


**Obstetric outcome in labouring patients with intravenous tramadol and epidural analgesia with ropivacaine**

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Effective analgesia attenuates or eliminates pain in labour. Use of tramadol for labour analgesia has been recommended but sufficient data on its intravenous use as analgesia during labour is not available.

## Obstetric outcome in labouring patients with intravenous tramadol and epidural analgesia with ropivacaine

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### Abstract

**Background:** Effective analgesia attenuates or eliminates pain in labour. Use of tramadol for labour analgesia has been recommended but sufficient data on its intravenous use as analgesia during labour is not available. Hence this study was designed to investigate safety and efficacy of analgesia using tramadol and compare it with epidural analgesia using ropivacaine in laboring parturients.

**Materials and Methods:** A comparative study was conducted on 100 laboring parturients, randomly allocated to group A receiving dose of tramadol: 1 mg/kg/body weight intravenous bolus followed by 100mg in 500ml ringer lactate drip 1/V and group B receiving epidural analgesia using 0.2% ropivacaine. Assessments were done for fetal heart rate abnormality, mode of delivery, duration of labour, Apgar Score. The VAS score for pain relief was calculated every 30 minutes in both the groups from 0 minutes to 8 hours.

**Results:** Group A had significant higher number of vaginal deliveries compared to group B ( $p < 0.01$ ) which had higher number of instrumental deliveries ( $p < 0.01$ ). No difference was observed in caesarean rate in both the groups. Pain relief was significant in patients of epidural group. The neonatal outcome was same in both the groups. Minimal adverse effects were seen in tramadol group.

**Conclusion:** Tramadol and epidural analgesia in labour is safe and effective. Although they do not increase the caesarean rate but epidural analgesia does increase instrumental deliveries significantly.

**Key Words:** *epidural analgesia, labour, tramadol, vaginal delivery, instrumental delivery*

## Introduction

Pain relief is an important issue for women in labour. Effective analgesia attenuates or eliminates pain in labour.<sup>1</sup> Among the various methods of pain relief, epidural analgesia has been reported to be a safe and satisfactory method. Tramadol also provides effective analgesia and has a low risk of respiratory depression. Use of tramadol for labor analgesia has been recommended but there has not been sufficient data on its intravenous use as labor analgesia.<sup>2</sup> Hence this study is designed to investigate safety and efficacy of analgesia using tramadol and compare it with epidural analgesia using ropivacaine in laboring parturients.

## Materials and Methods

A comparative study was conducted on 100 women admitted in labor room for delivery of tertiary care hospital in Punjab. They were informed about pain relief during labor using analgesia, their willingness and written consent was taken. Parturients were allocated to two groups by method of randomization. Group A (receiving dose of tramadol: 1 mg/kg/body weight intravenous bolus followed by 100mg in 500ml ringer lactate drip I/V) and group B receiving epidural analgesia using 0.2% ropivacaine.

Inclusion criteria being gestational age 37-41wks, primipara/multipara during active stage of labor >3cm, vertex presentation and spontaneous or induced labor, women without any obstetric complication. Exclusion criteria being contraindications to epidural analgesia, any medical complications (diabetics, asthma, hypertensive disorder of pregnancy, heart disease, epilepsy) and drug/medication abuse.

Haemogram and coagulation profile was done. Experienced anesthesiologist gave an epidural test dose of 3 ml of lignocaine, 2% with epinephrine 1:200,000 to patients in group B. Five minutes later, after confirming a negative response to this test dose, analgesia was initiated using 2ml increments of ropivacaine 0.2%, repeated at 10min and 20min. A continuous epidural infusion using the patient controlled epidural analgesia (PCEA) infusion device with the same drug was started at a rate of 6-10 ml/h to maintain an adequate analgesia. The PCEA infusion device was programmed with the standardized parameters of a 2ml bolus and a 10-min lockout period using the study solution. Additional epidural analgesic study solution (2ml) was delivered by the patient by pressing the demand PCEA device, when desired or when VAS more than 5. Assessments were made in both groups every 10 min for the first 30 min, and finally every 30 min till delivery. Parturient appraisal included assessment of non invasive blood pressure (NIBP), pulse rate, fetal heart rate, oxygen saturation and pain relief completion of a 10 cm linear visual analog scale for pain (VAS) at the peak of contractions (0 no pain; 10 worst pain imaginable). Any fetal heart rate abnormalities was assessed and managed accordingly. Duration of each stage of labor; 1<sup>st</sup> stage (from start of labor to full dilatation of cervix), 2<sup>nd</sup> stage (from full dilatation of cervix to delivery of neonate), 3<sup>rd</sup> stage (till delivery of placenta and membranes), total duration of labor, mode of delivery i.e. spontaneous /forceps /ventouse /lower segment caesarean section(LSCS), indication of assisted delivery, duration and rates of epidural infusion and I/V tramadol, number and dose of supplementary top ups, Apgar Score, neonatal birth weight, patient satisfaction score was recorded. Adverse effects such as hypotension, nausea/vomiting, leg weakness, shivering, drowsiness, backache were recorded.

Analgesia by either technique will be started after establishment of active stage of labor i.e. cervix is > 3cm dilated.

Study protocol was approved by **ethical committee** of the institution.

### Statistical Analysis

Mean and standard deviation were computed. The difference between two groups was seen by applying t-test. The level of significance considered was 0.05.

### Results

The mean age at presentation was  $28 \pm 5$  years. A majority (75%) belonged to urban area and 25% to the rural area. There was no significant difference in number of primigravida and multigravida amongst the groups (60% and 40% in group A, 69% and 31% in group B respectively). Significantly more number of patients needed induction of labour in epidural group compared to group A (88% vs 70%). The duration of 1st stage (401.3 min vs 387.7 min), second (33.68 min vs 34.74 min) and third stage (11.14 vs 11.00 min) in both the groups was comparable. Total duration of labour in two groups was 445.62 min and 434.28 min respectively. Table I shows mode of delivery. Group A had significant higher number of vaginal deliveries compared to group B (66% vs 40%,  $p < 0.01$ ) which had significantly more number of instrumental deliveries (36% vs 12%,  $p < 0.01$ ). The number of cesarean section was almost same in both the groups, most common cause was fetal distress.

**Table I: Percentage of patients with mode of delivery in both the group**

Mode of delivery	Group A n=50	Group B n=50
Instrumental	12	36**
Vaginal	66	40**
LSCS	22	24

Group A vs Group B, \*\*  $p < 0.01$

**Table II: Comparison of VAS score in both the groups**

VAS	Group A	N	Group B	N
0 min	$9.78 \pm 0.68$	50	$6.88 \pm 2.4^{***}$	50
10 min	$9.14 \pm 1.2$	50	$3.80 \pm 2.5^{***}$	50
20 min	$8.10 \pm 0.65$	50	$3.05 \pm 2.0^{***}$	50
30 min	$7.05 \pm 0.3$	50	$2.56 \pm 1.6^{***}$	50
1 hr	$8.02 \pm 0.4$	50	$2.72 \pm 1.5^{***}$	50
2 hr	$8.20 \pm 0.6$	46	$2.84 \pm 1.5^{***}$	49
3hr	$8.28 \pm 0.9$	39	$3.00 \pm 1.7^{***}$	46
4hr	$8.72 \pm 0.9$	32	$3.03 \pm 2.2^{***}$	31
5hr	$8.83 \pm 0.9$	23	$2.64 \pm 1.7^{***}$	25
6hr	$9.08 \pm 0.8$	13	$2.58 \pm 1.4^{***}$	19
7hr	$8.80 \pm 0.8$	10	$2.50 \pm 1.0^{***}$	14
8hr	$9.25 \pm 0.9$	8	$2.0^*$	2

Group A vs Group B, \*\*\*  $p < 0.001$

**Table III: Comparison of Apgar Score in both the groups at 1 minute**

APGAR- 1 MIN							p-value
		5	6	7	8	9	
Group A n=50	Count	1	2	5	41	1	0.441
Group B n=50	Count	4	1	2	41	2	
Total	Count	5	3	7	82	3	
	Percentage	100.0%	100.0%	100.0%	100.0%	100.0%	

The VAS score was calculated every 30 minutes from 0 minutes to 6 hours. Pain relief was highly significant ( $p < 0.001$ ) in patients of epidural group (Table II). The neonatal outcome was similar in both the groups. Apgar Score was compared at 1 minute and 5 minute in both groups and was not significantly different (Table III). Regarding adverse effects of both analgesia, non significant hypotension, drowsiness and shivering was noted in all the patients. Leg weakness and backache was also noted in few patients, but significantly higher number of women in group A suffered from vomiting (24% vs 0%) Table IV

**Table III: Comparison of Apgar Score in both the groups at 5 minutes**

APGAR- 5 MIN						p-value
		7	8	9	10	
Group A n=50	Count	1	2	5	41	0.901
Group B n=50	Count	4	1	2	41	
Total	Count	5	3	7	82	
	Percentage	100.0%	100.0%	100.0%	100.0%	

**Table IV: Adverse effects**

Adverse effects	Groups	
	Tramadol	Epidural
Vomitings	24.0%	0%**
Hypotension	100.0%	100.0%
Leg weakness	0.0%	2%
Drowsiness	100.0%	100.0%
Backache	4.0%	6%
Shivering	100.0%	100%

Group A vs Group B, \*\* p< 0.01

## Discussion

Pain and agony during child birth is quite often unbearable and at times lead to maternal and fetal sequelae, because of widespread maternal sympathetic activation that causes increase in cardiac output, blood pressure and pulse rate. Painful labour also reduces uteroplacental blood flow by 25%.<sup>3</sup> Effective analgesia is not only a great relief to laboring mother but also prevents pain induced hyperventilation and hypocapnia during labour.<sup>4</sup> Safety and efficacy of two different types and modes of analgesia during labor was studied and compared.

Successful vaginal deliveries were significantly more in group A as compared to group B which had more instrumental deliveries. So in our study epidural analgesia was associated with increased risk of instrumental vaginal birth which may be because of poor maternal bearing down efforts and longer second stage of labour.<sup>5</sup> Other workers have also reported similar findings.<sup>6</sup> Although Jaitely A et al did not find any significance effects on mode of delivery using both types of analgesia.<sup>7</sup> Number of cesarean section was almost same in both the groups and is similar to the number otherwise generally observed without use of labor analgesia. Similar findings have been reported by other studies.<sup>8-10</sup> There was no significant difference observed in duration of labor in each stage or total duration in both the groups as shown by other workers also.<sup>7,8,10</sup>

The VAS score was compared in both the groups. Pain relief was highly significant in epidural group, similar results are concluded by others as well.<sup>6-7</sup> Neonatal outcome was not affected by any type of analgesia. Apgar score in both the groups was comparable. Similar results were observed by other workers.<sup>11-12,7</sup>

The adverse side effects were minimal. Tramadol group only had some vomiting and rest of the side effects were comparable, making it safe and effective labour analgesia.<sup>2,13</sup>

### Conclusion

Tramadol and epidural analgesia in labour is safe and effective and does not increase the caesarean rate. Epidural analgesia only increase instrument deliveries compared to tramadol I/V.

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