

**LABOR ANALGESIA: A COMPARATIVE STUDY OF INTRAVENOUS PARACETAMOL VERSUS INTRAMUSCULAR TRAMADOL IN ITS SAFETY AND EFFICACY**

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**ABSTRACT:**

**Title:** Labor analgesia: a comparative study of intravenous paracetamol versus intramuscular tramadol in its safety and efficacy.

**Objectives:** This study aimed to compare the efficacy and safety of intravenous paracetamol (1000mg) and intramuscular tramadol (100mg) as labor analgesic.

**Methods:** A prospective randomized study was conducted on 120 women in active labor at NIMS Hospital, Jaipur, between January and September 2023. Patients were divided into two groups: Group A received intravenous paracetamol, and Group B received intramuscular tramadol. Labor progression, pain intensity (according to McGills scale), perinatal outcomes, and maternal side effects were monitored.

**Results:** Paracetamol was found to be more effective in pain relief than tramadol. After 1 and 3 hours, paracetamol demonstrated superior pain relief. After 3 hours, 70% cases of Group A had significant pain relief as compared to 40% cases of Group B. The total duration of labor from the active phase of first stage of labor was 4.55 hours in Group A and 6.46 hours in Group B. Both drugs showed no significant difference in neonatal outcomes. Nausea and vomiting were the primary maternal adverse effects, with tramadol displaying a slightly higher incidence, though the difference was not statistically significant.

**Conclusion:** In conclusion, intravenous paracetamol is a more effective and safer labor analgesic compared to intramuscular tramadol. It offers superior pain relief, shortens the duration of labor, and has fewer maternal side effects. These findings suggest that intravenous paracetamol can be a valuable option for labor analgesia in low-resource healthcare settings in developing countries, contributing to a more positive childbirth experience for mothers.

**Keywords:** paracetamol, tramadol, analgesia

**INTRODUCTION:**

‘Delivery of an infant into the arms of a conscious and pain free mother is one of the most exciting and rewarding moments in medicine.’<sup>(1)</sup> Labor pain is the most excruciating pain experienced by women which can be distressing and not easily forgotten inspite of the pleasure that accompanies the newborn. Labor pain is associated with hyperventilation, maternal respiratory alkalosis, release of catecholamines, uterine vasoconstriction, fetal acidemia and incoordinate uterine contractility, affecting the maternal and perinatal outcome<sup>(2)</sup>. Hence in the absence of a medical contraindication, maternal request should be sufficient for labor analgesia.

A realm of very effective anesthetic agents are suitable for labor analgesia at present especially regional anesthesia which is considered as a gold standard in developed countries, but it also requires costly equipments, continuous monitoring facilities and expert anesthesiologists which is difficult to acquire in our developing country. There is a need of drugs which are low cost, easily available with no special administration technique required which do not adversely affect the perinatal outcome. Hence drugs like paracetamol and tramadol are a boon for labor analgesia.

Paracetamol or acetaminophen increases the pain threshold by inhibiting both the isoforms of cyclooxygenase enzymes which are involved in prostaglandin synthesis. Tramadol is a centrally acting opioid analgesic.<sup>(3)</sup> This study was undertaken to compare the efficacy and study the safety profile of single dose 1000mg paracetamol given intravenously with 100mg tramadol given intramuscularly as labor analgesic during the active phase of labor.

## **MATERIALS AND METHODS:**

The present study was a single blinded prospective randomized study conducted in 120 women in the Department of Obstetrics and Gynecology, NIMS Hospital Jaipur during January 2023 to September 2023.

### **Inclusion criteria:**

- Gestation of more than 37 weeks
- Singleton live fetus
- Cephalic presentation
- Spontaneous onset of labor
- In active stage of labor with cervical dilatation of 4cm

### **Exclusion criteria:**

- Cephalopelvic disproportion
- Premature rupture of membranes
- Previous cesarean section or previous uterine surgeries
- Hemoglobin <8g/dl
- Antepartum haemorrhage
- H/O Drug allergy
- Fetal distress
- Medical disorders eg- cardiac disease, liver disease, renal disease, patient on anticonvulsants

Detailed history, general and obstetric evaluation including vaginal examination was done, required investigations were sent. After taking informed consent, the women were randomly divided into 2 groups-

**GROUP A:** Paracetamol group: They were given 100 ml of 1000mg intravenous paracetamol infusion over 15 minutes.

**Group B:** Tramadol group: They were given injection tramadol hydrochloride 100mg in outer upper quadrant of gluteal region.

Labor was monitored using partogram. Pain intensity before drug administration, 1 hour and 3 hours after drug administration was measured using MC GILL pain intensity scale.

MC GILL PAIN SCALE	PAIN INTENSITY
Nil	0
Mild	1
Discomfort	2
Distressing	3
Horrible	4
Excruciating	5

Duration of active phase of first stage of labor, second stage of labor, perinatal outcome and maternal side effects were noted in both groups. The women for whom LSCS was decided, were excluded from the study as we wanted to compare the duration of labour.

Data was described as mean ±SD and percentage. Metric data was compared by Student’s t test whereas non-metric data compared by chi square test. The p value <0.05 was considered as significant.

**RESULTS:**

The table no. 1 compares both the groups in variables of age, gestational weeks and the cervical dilatation at the time of drug delivery. The p values are 0.84, 0.340 and 1 respectively which are non-significant.

**TABLE 1: DISTRIBUTION OF CASES ACCORDING AGE, GESTATIONAL AGE AND CERVICAL DILATATION**

VARIABLES	GROUP A	GROUP B	p VALUE
Age (years)	25.3±2.5	25.1±2.7	0.84(Non- significant)
Gestational Age (weeks)	38±1	38.7±1	0.340(Non- significant)
Cervical dilatation (cm)	4	4	1(Non- significant)

The table no. 2 shows that the p-value for McGill pain intensity before drug administration was statistically insignificant (0.774).

After 1 hour of drug administration, in Group A, 3.34% had mild pain, 13.34% cases had discomfort, 66.67% had distressing pain while 16.67% had horrible pain. Whereas in Group B, 13.34% cases had mild pain, 6.67% had discomfort, 33.34% had distressing pain and 46.67% had horrible pains. The p-value is 0.01 which is significant.

After 3 hours of drug administration, in Group A, 70% had no pains, 20% had mild pains, 3.34% cases had discomfort, 3.34% had distressing pains and 3.34% had horrible pains. In Group B, 40% had no pain, 6.67% had mild pain, 20% cases had discomfort, 16.67% had distressing pains and 16.67% had horrible pains.

**TABLE 2: DISTRIBUTION OF CASES ACCORDING TO MC GILL PAIN INTENSITY BEFORE, AFTER 1 HOUR AND AFTER 3 HOURS OF DRUG ADMINISTRATION**

TIME	PAIN INTENSITY	GROUP A	GROUP B	p VALUE
Before drug administration	NIL	0	0	0.7741 (Non-significant)
	MILD	0	0	
	DISCOMFORT	20 (33.34%)	18 (30.00%)	
	DISTRESSING	30 (50.00%)	26 (43.33%)	
	HORRIBLE	10 (16.67%)	14 (26.67%)	
	EXCRUCIATING	0	0	
After 1 hour of drug administration	NIL	0	0	0.01 (Significant)
	MILD	2 (3.34%)	8 (13.34%)	
	DISCOMFORT	8 (13.34%)	4 (6.67%)	
	DISTRESSING	40 (66.67%)	20 (33.34%)	
	HORRIBLE	10 (16.67%)	28 (46.67%)	
	EXCRUCIATING	0	0	
After 3 hours of drug administration	NIL	42 (70.00%)	24 (40.00%)	0.01 (Significant)
	MILD	12 (20.00%)	4 (6.67%)	

	DISCOMFORT	2 (3.34%)	12 (20.00%)
	DISTRESSING	2 (3.34%)	10 (16.67%)
	HORRIBLE	2 (3.34%)	10 (16.67%)
	EXCRUCIATING	0	0

**TABLE3: DISTRIBUTION OF CASES BASED ON DURATION OF LABOR**

DURATION OF LABOR	GROUP A	GROUP B	p VALUE
Active phase of first stage of labor (hours/min)	4.01±0.81/ 240±48.6	5.75±0.64/ 345±38.4	0.0001 (Significant)
Second stage of labor (min)	25.5±4.78	35.5±4.9	0.0001 (Significant)
Third stage of labor (min)	7.6±1.3	7.4±1.9	0.787 (Non-significant)
Total duration of labor (hours/min)	4.55±0.91/ 273.1±54.6	6.46±0.75/ 387.9±45.2	0.0001 (Significant)

The mean duration of the active phase of first stage of labor in Group A was 4.01±0.81 hours and Group B was 5.75±0.64 hours and p-value was 0.0001 which is significant. The mean duration of second stage of labour for Group A was 25.5±4.78 minutes and Group B was 35.5±4.9 minutes and the p-value was 0.0001 which is significant. For the duration of third stage of labor, the p-value was 0.787 which is non-significant.

The total duration of labour in Group A was 4.55±0.91 hours and in Group B was 6.46±0.75 hours, the p-value being 0.0001.

**TABLE 4: DISTRIBUTION OF CASES ACCORDING TO APGAR SCORE**

	GROUP A	GROUP B	p VALUE
1 MIN	6.3±0.70	6.5±0.56	0.48(Non-significant)
5 MIN	8.2±1.2	8.3±1.2	0.75(Non-significant)

In the table no. 4 we can see that the p-value for the APGAR score at the end of 1 minute and 5 minutes is 0.48 and 0.75 respectively which is non-significant.

**TABLE 5: DISTRIBUTION OF CASES BASED ON MATERNAL ADVERSE REACTIONS**

ADVERSE EFFECT	GROUP A	GROUP B	p VALUE
Nausea	4 (6.67%)	6 (10.00%)	0.145 (Non-significant)
Vomiting	0	4 (6.67%)	0.182 (Non-significant)
Respiratory depression	0	0	-
Fetal tachycardia/bradycardia	0	0	-
PPH	0	0	-

In the table no. 5 we can see that in Group A, only nausea was seen in 6.67% and in Group B nausea was seen in 10.00% cases and vomiting in 6.67% cases. Other adverse effects such as respiratory depression, fetal tachycardia/ bradycardia and PPH were not observed in either of the groups.

**DISCUSSION:**

Labour pains are a major cause of stress and anxiety for the parturient mother and it adversely affects both the maternal and fetal outcomes. Hence an efficient, cost-effective and safe labour analgesic is required in a developing country like ours. Both, intravenous paracetamol and intramuscular tramadol fulfil the above criterias and our aim was to compare both of them in terms of various maternal and fetal parameters.

In Table 1, we compared both the groups in terms of maternal age, gestational weeks and cervical dilatation at the time of drug administration. The p-value for all the variables was insignificant indicating homogenous distribution of patients in both the groups without any bias, making the study reliable.

In Table 2, we see the distribution of the cases before, after 1 hour and after 3 hours of drug administration according to the McGill pain intensity scale. There is no statistical difference in the cases before drug administration. On comparing the groups after 1 and 3 hours of drug, administration it was found out that the p-value was 0.01 (significant) proving that paracetamol has a better analgesic effect than tramadol. About 70% cases from Group A had substantial relief after 3 hours as compared to 40% from Group B. this might be explained by the fact that the peak analgesic effect of paracetamol is seen at 1 hour and effect lasts for 4-6 hours while for tramadol, the onset is within 10 minutes and action lasts for 2-3 hours.<sup>0</sup> Similar observations were made by studies such as Lallar et al<sup>(4)</sup> and Hema Mohan et al<sup>(5)</sup> i.e. paracetamol was a better analgesic than tramadol after 1 and 3 hours of administration.

In Table 3, we observed that the mean duration of the active phase of first stage of labor in Group A was 4.01±0.81 hours and Group B was 5.75±0.64 hours. The mean duration of second stage of labour for Group A was 25.5±4.78 minutes and Group B was 35.5±4.9 minutes and the p-value was 0.0001 which is significant. There is no significant difference in

the duration of third stage of labor. The total duration of labour in Group A was  $4.55 \pm 0.91$  hours and in Group B was  $6.46 \pm 0.75$  hours, the p-value being 0.0001.

This proves that intravenous paracetamol significantly reduces the active phase of first stage of labour and second stage of labour, hence reducing the total duration of labour, when compared to intramuscular tramadol. A probable reason for this could be that tramadol causes sedation, although lesser than other opioids, leading to lesser mobility of women in labor which could lengthen the labor.

Our study results are similar to Lallar et al<sup>(4)</sup> in which the total duration was  $4.3 \pm 0.7$  hours in Group A and  $5.9 \pm 0.7$  hours in Group B and p-value being 0.000 which is significant. Also the study by Jeetendra Kaur et al<sup>(6)</sup> corroborates that paracetamol decreases the total duration of labor.

In Table 4, we can see that the p-value for the APGAR score at the end of 1 minute and 5 minutes is 0.48 and 0.75 respectively which is non-significant. Hence it can be safely concluded that both paracetamol and tramadol are safe for the baby. No added intensive fetal monitoring was required after administration of these drugs, proving them to be of use in low resource settings. Similarly, Lallar et al<sup>(4)</sup> and Jeetendra Kaur et al<sup>(6)</sup> in their studies also showed that no neonatal adverse outcomes were observed.

In Table 5 we can see that in Group A, only nausea was seen in 6.67% and in Group B nausea was seen in 10.00% cases and vomiting in 6.67% cases. No other side effects like respiratory depression, fetal tachycardia/ bradycardia and PPH were noted in either of the groups. Tramadol has a higher incidence of nausea and vomiting as compared to paracetamol but the difference is statistically insignificant. In the study by Lallar et al<sup>(4)</sup> in Group A, nausea was seen in 2.2% followed by vomiting in 1.1% and in Group B, nausea was the most common side effect i.e. 6.4% followed by vomiting in 4.3%. the differences in this study were also statistically insignificant. Hence no serious adverse effects were observed in either of the groups.

## CONCLUSION:

Obstetric analgesia strives at making childbirth a pleasurable and painless event. Findings from the present study demonstrate that intravenous paracetamol is a more effective labor analgesia than intramuscular tramadol. Paracetamol also has a better analgesic effect, aids in shortening the duration of labor and has fewer maternal adverse effects than tramadol. However the neonatal outcome of both the drugs is favourable. Hence in developing countries with low resource health care settings, intravenous paracetamol can be effectively used as labor analgesic.

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