

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20234086>

## Original Research Article

# Efficacy and safety of intravenous paracetamol versus intravenous tramadol for labour analgesia

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**Received:** 04 November 2023

**Accepted:** 01 December 2023

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## ABSTRACT

**Background:** An effective labour analgesia improves maternal and perinatal outcome and improves the course of labour.

**Methods:** This was a prospective, randomised study done to compare effectiveness and safety of intravenous infusion of paracetamol with tramadol when used for labour analgesia. Group A (25 parturients) received paracetamol 1000 mg and group B (25 parturients) received tramadol 1mg/Kg at 4 to 6 cm cervical dilatation. Visual analogue score for pain was assessed at the baseline, 1 hour and 3 hours of drug administration and was compared between the two groups along with various maternal and fetal outcomes.

**Results:** The difference in mean Visual Analogue Score (VAS) just before the drug administration was not statistically significant. However, at 1 hour of drug administration, mean VAS was significantly lower in the Group A (4.60) in comparison to Group B (5.82). The mean VAS at 3 hours was slightly lower in group A (6.35) in comparison to group B (6.65), though statistically there was no significant difference. Nausea, vomiting and sedation were found to be more in the tramadol group as compared to paracetamol group. The mean 1 and 5 minute apgar scores were found to be comparable in both the groups.

**Conclusions:** So, it can be concluded from our study that intravenous paracetamol may be preferred over intravenous tramadol as it is associated with better analgesic efficacy and less maternal side effects. Although both the drugs were found to have good neonatal outcome.

**Keywords:** Labour analgesia, Paracetamol, Visual analogue score

## INTRODUCTION

Labour is characterised by painful and regular contractions of uterus which progressively increase in its intensity until the delivery of the fetus. Labour pains are considered as intolerable pain by most of the women undergoing childbirth and it ranks higher on various scales for measuring pain in contrast to other types of pain.<sup>1</sup> Labour pains are subjective and give emotional experience to the women. During labour, both visceral and somatic pain components are present.

Various physiological responses to labour pain may influence progress of labour and can have deleterious effects on parturient and fetus. Maternal discomfort and stress of childbirth can cause maternal release of catecholamines and hyperventilation. Release of maternal catecholamines can lead to vasoconstriction, thus decreasing uteroplacental blood flow. These consequences associated with labour pain can be minimized by providing optimal labour analgesia.

Providing effective as well as safe labour analgesia has

been an ongoing challenge. Broadly labour analgesia modalities can be divided into –pharmacological and non-pharmacological types. “Neuraxial analgesia (i.e., epidural, spinal, combined spinal- epidural) is the most efficacious, versatile method in providing labour analgesia and is considered the gold standard method”.<sup>2</sup> It is the most widely used labour analgesic globally.<sup>3</sup> Neuraxial analgesia should be offered to all the woman who desire pharmacological labour analgesia, in the absence of any contraindications.<sup>3</sup> Providing neuraxial analgesia to all the parturients may not be feasible in places with constraints of expensive equipment, shortage of manpower and facilities for continuous maternal and fetal monitoring. Even inspite of having 24 hours anesthetist facility in obstetrics units which can provide a wide range of analgesia options, neuraxial anaesthesia cannot be assured to all the parturients due to high demand and limitation of staff as well as resources.<sup>4</sup>

Considering all the limitations and contraindications in providing neuraxial analgesia to parturients in providing labour analgesia, systemic labour analgesics plays an important role especially in developing countries like India. Parenteral or systemic analgesics do not require anesthesiologists or skilled care workers and they are virtually always accessible in all settings of maternity care. Systemic labour analgesics like opioid and their derivatives e.g., meperidine, tramadol are being commonly used drugs wherever neuraxial analgesia is not feasible or is contraindicated. Paracetamol is an effective as well as safe analgesic being routinely used now for relieving pain in acute ailments, post-operative pain, and as an adjunct to other analgesics.<sup>5</sup> So, the current study was planned to compare effectiveness and safety of paracetamol versus tramadol for labour analgesia in the active phase of labour.

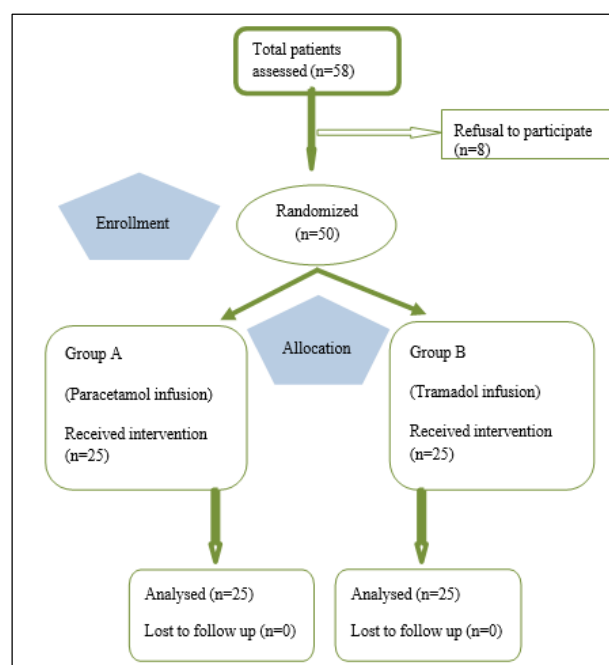
## METHODS

The research was done in the Department of Obstetrics and Gynaecology with the Department of Anaesthesia, Government Medical College and Hospital, Sector 32 Chandigarh. Fifty parturients admitted in the labour room for vaginal delivery in the active phase of labour (at cervical dilatation 4 to 6 cm) at term gestation fulfilling the inclusion criteria were enrolled in the study once the institutional ethics committee gave its approval. Informed written consent was given by each patient. It was a prospective randomized trial. After taking informed consent, 50 patients were allocated into 2 groups of 25 each by computer generated random number table.

Various inclusion criterias were patients for intended vaginal delivery in active stage of labour with dilatation of cervix from 4-6 cm, gestational age (37-41 weeks), spontaneous or induced labour, age (18-35 years), primigravida/ multigravida (upto parity 1), singleton pregnancy with viable fetus, vertex presentation, patients not a candidate for neuraxial analgesia for various reasons (not willing/ presence of contraindications, etc.), non scarred uterus. Various exclusion criterias were patients

with pre pregnancy medical disorders (pregestational diabetes mellitus, rheumatic heart disease, chronic hypertension, severe anaemia, liver disease, renal disease and epilepsy) and some obstetric complications (preclampsia, eclampsia, GDM on insulin, antepartum haemorrhage, polyhydramnios, intrauterine growth restriction and chorioamnionitis).

Fifty cases were enrolled in the active phase of labour (4-6 cm cervical dilatation) from labour room of the Department of Obstetrics and Gynaecology fulfilling the inclusion and exclusion criterias and willing to take part in the study. Demographic details and a detailed history of the present pregnancy, medical history and obstetric history were recorded. Clinical examination including obstetrical examination and pervaginum examination was done. Labour details before recruitment in the study was also noted. All investigations done during pregnancy were recorded on the pre designed data collection sheet. CTRI registration was taken (CTRI/2020/06/025866).



**Figure 1: Consort diagram.**

Random sequences were generated to allocate study subjects into two groups by using computer generated random number tables. Patients enrolled in the study received either paracetamol infusion (1000mg) or tramadol infusion (1mg/Kg body weight) given over 20 minutes for labour analgesia. Before giving paracetamol and tramadol infusion, baseline VAS (Visual analogue score) was assessed. Hence, two groups of enrolled patients were created in the study: Group A (n=25)- Patients who received injection paracetamol 1000 mg in 100 ml Normal saline in intravenous infusion over 20 minutes. Group B (n=25)- Patients who received injection tramadol 1mg/Kg of body weight in 100 ml normal saline in intravenous infusion over 20 minutes. VAS (Visual

analogue score) for pain assessment was repeated at 1 hour and 3 hour after giving labour analgesia.<sup>6</sup> Labour was monitored by using partogram. Maternal and fetal monitoring was done according to labour room protocols.

In case the parturient desired more analgesia, then appropriate analgesic was given according to maternal and fetal condition in both the groups as additional analgesia and patient was excluded from the study. Duration of active phase of first stage of labour, duration of second stage of labour, fetal bradycardia, mode of delivery, respiratory depression in baby, neonatal Apgar score, NICU admissions in both groups was noted and all the parturients were followed till the time of discharge from the hospital. VAS score was compared in both the groups at baseline, 1 hour and 3 hour and also the side effects in both groups were compared. Duration of Active phase of first stage of labour, duration of second stage of labour, fetal bradycardia, respiratory depression in baby, neonatal Apgar score, NICU admissions were compared in both the groups.

### Statistical analysis

Response rates for 2 groups were compared by using normal tests of proportions. Pain scores in 2 groups was described by using mean and standard deviation. Students t test in case of normal distribution was used for comparing pain scores in the 2 groups and in case of non normal distribution. Mann-Whitney U test was used for comparison of means. Chi square test of significance was used for testing significance of association between pain categories and patient characteristics with drugs to be administered.

Other quantitative parameters in the study were compared by using Students t test/ Mann-Whitney U test. Subsequent changes in outcome parameters were tested for significance of changes by using paired t test for quantitative parameters and Wilcoxon signed rank test for non normal data for 2 drug groups. Data analysis was carried out by using SPSS25.0 software. This study was conducted on ethical guidelines for biomedical research on human subject as given in the "Declaration of Helsinki" and by Central Ethics Committee on Human Research (CEHER) of ICMR, New Delhi. A written and informed consent was taken from all. The interventions used in the current study were entirely safe. The subjects were informed of the study's goals, methodology, potential findings, demands, discomforts, inconveniences, and risks that they might experience. The participants personal details were kept confidential. The patients were given the right to opt out of the study whenever they wish without any bearing on the treatment to be given.

## RESULTS

The mean age of parturients in group A and B was 25.56 years and 26.56 years respectively. Mean age was found to be comparable between the two groups ( $p=0.479$ ).

In group A -16% of the parturients belonged to lower socioeconomic strata, 60% belonged to lower middle and 24% belonged to upper middle strata. Whereas in group B -20 % of the parturients belonged to lower socioeconomic strata, 56% belonged to lower middle, 4% belongs to upper lower and 20% belonged to upper middle strata. In group A -12% were illiterate, 24% had primary level, 52% had secondary level of education and 12% were graduate and above whereas in group B - 40% had primary, 56% had secondary level of education and 4% were graduate and above. Thus, both of the groups were also comparable in terms of socioeconomic strata and the level of education, p values being 1.000 and 0.188 respectively.

Out of 50 patients, 15 patients were primigravida and 10 patients were second gravidas in group A and 16 patients were primigravida and 9 patients were second gravidas in group B and there was no statistically significant difference ( $p=0.771$ ). As per the inclusion criteria of our study, we recruited only patients upto parity one.

The mean pre - pregnancy BMI in group A and group B was 23.78 Kg/m<sup>2</sup> and 22.84 Kg/m<sup>2</sup> respectively and there was no statistically significant difference among the two groups ( $p=0.207$ ). The current weight (weight at the time of recruitment in the study) of the recruited patients was also comparable among the two groups ( $p=0.609$ ).

The average gestational age at the time of recruitment in group A was 38.80 weeks whereas in group B it was 38.90 weeks and the difference between the two groups was statistically insignificant (Table 1).

**Table 1: Maternal characteristics.**

Variables	Group A (n=25)	Group B (n=25)	p-value
Mean age (years)	25.56	26.56	0.479
Pre-pregnancy BMI (Kg/m <sup>2</sup> )	23.78	22.84	0.207
Weight (Kg)	71.00	70.16	0.609
Mean gestational age (in weeks)	38.80	38.90	0.762

The mean cervical dilatation at the time of drug administration in group A and group B was 4.60±0.76 and 4.68±0.69 respectively and difference was not statistically significant in between the two groups ( $p=0.699$ ). Similarly, difference in the mean cervical effacement was not statistically significant among the two groups ( $p=0.545$ ).

The mean Visual Analogue Score (VAS) just before the drug administration was 8.34±1.12 in Group A and 8.04±1.20 in Group B and difference was statistically insignificant ( $p=0.368$ ). At 1 hour of drug administration, Mean VAS was significantly less in the Group A (4.60±1.38) as compared to Group B (5.82±1.30), and the difference in VAS score between the two groups was statistically significant ( $p=0.002$ ). However, at 3 hours of

drug administration, mean VAS was comparable in both the groups ( $p=0.475$ ), being  $6.35\pm1.26$  in Group A and  $6.65\pm1.22$  in Group B respectively. 5 patients in Group A

and 8 patients in Group B delivered before 3 hours of drug administration (Table 2). None of the patients required or asked for additional analgesia.

**Table 2: Average VAS of patients in both groups at various time periods.**

Mean VAS	Group A			Group B			P value
	N	Mean	Standard deviation	N	Mean	Standard deviation	
<b>Just before the drug administration</b>	25	8.34	1.12	25	8.04	1.20	0.368
<b>At 1 hour</b>	25	4.60	1.38	25	5.82	1.30	0.002
<b>At 3 hours</b>	20	6.35	1.26	17	6.65	1.22	0.475

**Table 3: Categorization of pain intensity (VAS) at various time periods.**

Pain status		Group				P value
		Group A		Group B		
		N	%	N	%	
Before drug administration	n=50	n=25		n=25		1.000
Mild pain	0	0	0.0	0	0.0	
Moderate pain	5	2	8.0	3	12.0	
Severe pain	45	23	92.0	22	88.0	
At 1 hour of drug administration	n=50	n=25		n=25		0.003
Mild pain	7	7	28.0	0	0.0	
Moderate pain	33	16	64.0	17	68.0	
Severe pain	10	2	8.0	8	32.0	
At 3 hour of drug administration	(n=37)	(n=20)		(n=17)		0.630
Mild pain	0	0	0.0	0	0.0	
Moderate pain	19	11	55.0	8	47.1	
Severe pain	18	9	45.0	9	52.9	

Before the drug administration: In Group A, 8% had moderate pain and 92% had severe pain intensity. In group B, 12% had moderate pain and 88% had severe pain intensity and both the groups were comparable ( $p=1.000$ ).

At 1 hour of drug administration: In Group A, 28% had mild pain, 64% had moderate pain and only 8% had severe pain whereas in Group B, 68% had moderate pain and 32% had severe pain. It was seen at 1 hour administration, pain intensity decreased significantly in the paracetamol group in contrast to tramadol group ( $p=0.003$ ).

At 3 hour of drug administration: 13 parturients delivered before 3 hours of drug administration. Out of 20 parturients in Group A; 55% had moderate pain and 45% had severe pain. Out of 17 parturients in Group B, 47.1% had moderate pain and 52.9% had severe pain. So, the pain intensity had not decreased significantly in both the groups ( $p=0.630$ ) (Table 3).

Before the administration of drugs in Groups A and B, the mean fetal heart rate (FHR) was comparable in both the groups ( $p=0.879$ ). Similarly, the mean fetal heart rate at 1 hour of drug administration was comparable among the two groups ( $p=0.528$ ). 5 patients in group A and 8 patients

in group B delivered before 3 hours of drug administration. The difference in the mean fetal heart rate in the remaining parturients at 3 hours and after 3 hours of drug administration was also not statistically significant ( $p$  values=0.529 and 0.280 respectively).

The mean interval from drug intake to delivery was slightly less in the group B ( $4.19\pm1.68$  hours) as compared to group A ( $4.52\pm1.81$  hours) but the difference was not statistically significant ( $p=0.513$ ). 1 patient in the paracetamol group had emergency cesarean section in view of fetal bradycardia and meconium stained liquor. Difference in the duration of first stage, active phase of first stage and second stage of labour in both the groups was not statistically significant;  $p$  values being 0.450, 0.506 and 0.852 respectively (Table 4).

Out of 25 patients in group A- 23 had normal vaginal delivery (NVD), 1 had outlet forceps application and 1 had emergency cesarean section (LSCS). And in group B-all 25 patients had normal vaginal delivery but the difference was non significant between the two groups ( $p=0.490$ ). Indication of outlet forceps in the group A was fetal-bradycardia with poor maternal bearing down efforts and in case of emergency caesarean section it was meconium

stained liquor with fetal-bradycardia.

With respect to maternal side effects, patients in Group B (n=13) which received tramadol infusion (1mg/Kg) had more incidence of side effects as compared to patients in

Group A (n=3) which received paracetamol infusion (1000mg) and the difference was statistically significant (p=0.002).

**Table 4: Mean duration of labour at various phases.**

Stages of labour	Group A			Group B			P value
	N	Mean	Standard deviation	N	Mean	Standard deviation	
Duration 1st stage (hours)	24	11.27	4.00	25	10.41	3.88	0.450
Duration of active phase of first stage of labour (hours)	24	4.53	1.58	25	4.24	1.48	0.506
Duration of 2 <sup>nd</sup> stage (minutes)	24	36.46	12.290	25	35.80	12.305	0.852
Interval from drug intake to delivery (hours)	24	4.52	1.81	25	4.19	1.68	0.513

**Table 5: Distribution of side effects among patients.**

Distribution of side effects	N	Group				P value
		Group A (n=25)		Group B (n=25)		
		N	%	N	%	
Maternal side effects						
No	34	22	88.0	12	48.0	0.002
Yes	16	3	12.0	13	52.0	
Side effects						
Atonic PPH	1	0	0.0	1	4.0	1.000
Nausea	6	2	8.0	4	16.0	0.663
Vomiting	8	1	4.0	7	28.0	0.054
Sedation	3	0	0.0	3	12.0	0.234
Other intrapartum events						
Meconium stained liquor without fetal bradycardia	2	1	4.0	1	4.0	1.000
Meconium stained liquor with fetal bradycardia	2	2	8.0	0	0.0	
Fetal tachycardia	0	0	0.0	0	0.0	

**Table 6: Comparison of neonatal outcomes in both the groups.**

Neonatal outcome	N	Group				P value
		Group A (n=25)		Group B (n=25)		
		N	%	N	%	
Apgar score						
At 1 minute						
≤7	2	1	4.0	1	4.0	1.000
>7	48	24	96.0	24	96.0	
Mean±SD		8.80±1.00		8.84±0.80		0.877
At 5 minute						
>7	50	25	100.0	25	100.0	-
Mean±SD		9.00±0.00		9.00±0.00		-
NICU admission required						
No	49	24	96.0	25	100.0	1.000
Yes	1	1	4.0	0	0.0	

Two patients had nausea and 1 had vomiting in Group A whereas only 1 patient had atonic postpartum haemorrhage (PPH), 4 had nausea, 7 had vomiting and 3 had sedation in

Group B. Vomiting was the most common adverse effect seen in both the groups followed by nausea. 2 patients had both nausea and vomiting in the tramadol group (Table 5).



None of the patients had fatigue and dizziness in either of the two groups. 1 patient had meconium stained liquor without bradycardia and 2 patients had meconium stained liquor with bradycardia in Group A whereas only 1 patient had meconium stained liquor without bradycardia in Group B and the difference among the two groups was statistically insignificant ( $p=1.000$ ). None of the patients developed fetal tachycardia (Table 5).

Only 1 neonate in Group A had Apgar score less than 7 at 1 minute of birth; similarly in Group B only 1 neonate had Apgar score of less than 7 at 1 min of birth. The mean Apgar score was comparable at 1 min in both the groups ( $p=0.877$ ). At 5 minutes of birth both the groups had mean Apgar score of 9.00 each. Only 1 neonate in Group A required Neonatal Intensive Care Unit (NICU) admission as the baby had developed clinical early onset neonatal sepsis (EONS) and received antibiotics for the same.

None of the baby in group B required NICU admission and difference in between the two groups with respect to NICU admission was statistically insignificant (Table 6).

None of the baby developed respiratory distress requiring reversal with naloxone.

## DISCUSSION

Provision of labour analgesia gives positive birth experience to the parturient and it also minimizes various neuroendocrine and cardiovascular responses in the parturient which are associated with this pain.<sup>7,8</sup>

The present study was a prospective randomized trial undertaken with an aim to evaluate efficacy and safety of intravenous infusion of paracetamol in comparison to the intravenous infusion of tramadol for labour analgesia.

When VAS was again assessed at 1 hour after the drug administration it was significantly less in the group which received intravenous infusion of paracetamol 1gm as compared to group which received intravenous infusion of tramadol 1mg/kg. The mean VAS at 3 hours of drug administration was lower in the paracetamol group in comparison to tramadol group but the difference was statistically insignificant.

After 1 hour of drug administration the mean VAS reached the lowest values in both the groups. The difference in the VAS score in both the groups at 1 hour may be explained because of the difference in the pharmacokinetics of the two drugs. In case of paracetamol, onset of action occurs in about 5 min, peaks at 40-60 minutes and lasts for 4-6 hours while in case of tramadol onset of action is within 10 minutes and duration of action lasts for 2-3 hours.

Almost similar results were found by Garg N et al and Das BP et al in their studies.<sup>9,10</sup> Similarly, Elbohoty et al in a study comparing paracetamol and pethidine as a labour analgesic found that the paracetamol was as efficacious as

pethidine in providing labour analgesia except at 15 minutes after the drug administration when the average VAS was significantly lower in the pethidine group ( $p=0.004$ ) and no reduction in VAS was seen after 3 hours in both the groups.<sup>11</sup>

The mean duration of first stage of delivery, second stage of delivery, and interval from drug intake to delivery was not statistically different in the two groups. Similar results were found in the research conducted by Aimakhu et al, in which it was seen that the difference in the average duration of labor was not found to be statistically significant when intramuscular paracetamol 600mg was compared with intramuscular tramadol 100mg.<sup>12</sup>

Incidence of maternal adverse effects like nausea, vomiting and sedation were found to be more in the tramadol group ( $n=13$ ) as compared to paracetamol group ( $n=3$ ) in our study and there was statistically significant difference. Similarly, Makkar et al found that sedation as the maternal side effect was seen more in the tramadol group in comparison to the paracetamol group.<sup>13</sup>

The mean Apgar score at 1 minute was not significantly different in the paracetamol group in comparison to the tramadol group being  $8.80 \pm 1.00$  and  $8.84 \pm 0.80$  respectively. The average Apgar score at 5 minutes of birth was same in the two groups ( $9.00 \pm 0.00$ ), thus indicating the neonatal safety profile of both the drugs. Only 1 baby required Neonatal Intensive Care Unit (NICU) admission in the paracetamol group because of clinical early onset neonatal sepsis (EONS) whereas no neonate required NICU admission in the tramadol group and the difference in NICU admissions was not statistically significant among the two groups ( $p=1.000$ ).

Although neuraxial analgesia is considered as the most efficacious when used as labour analgesic but because of various factors like accessibility to costly equipments, lack of adequate continuous monitoring facilities and lack of availability of experienced anaesthesiologists, it is not possible to provide neuraxial analgesia to all patients especially in developing countries.<sup>3</sup> As a result, research is directed towards finding a suitable alternative to neuraxial analgesia which is efficacious and safe to the mother and newborn. In developing countries like India, systemic analgesics can be a blessing where neuraxial analgesia cannot be given to all the parturients. They are less invasive, easily available, much cheaper, easy to administer and also do not require skilled care workers or any special monitoring facilities. Among parenteral opioids, tramadol has been found to have fewer side effects but with equal efficacy as compared to other opioids.<sup>14</sup> Recently, paracetamol has been found to be safe and more efficacious in providing labour analgesia as compared to tramadol. But studies regarding this are few.

One of the limitations in our study was that we had recruited patients up to parity 1 only and we had kept many exclusion criteria like patients with pre-pregnancy medical disorders

(pregestational diabetes mellitus, rheumatic heart disease, chronic hypertension, severe anaemia, liver disease, renal disease and epilepsy) and some obstetric complications (preclampsia, eclampsia, GDM on insulin, antepartum haemorrhage, polyhydramnios, intrauterine growth restriction and chorioamnionitis) which also forms a large group of patients requiring labour analgesia. As five patients in the paracetamol group and eight patients in the tramadol group delivered before 3 hours, so the comparison of VAS score, pain intensity and other outcomes at 3 hours of drug administration have been assessed in the rest of the patients only. Another limitation was that we had recruited patients at 4-6 cm dilatation only. Our study revealed that intravenous paracetamol in comparison to intravenous tramadol given for labour analgesia is more efficacious. Additionally, paracetamol was linked to much less adverse maternal effects, although neonatal outcome and safety were similar with use of both tramadol and paracetamol. But as the sample size was less in our study more large scale and multicentric studies are required to ascertain whether intravenous paracetamol or tramadol is better for labor analgesia in settings where epidural analgesia is not feasible because of any reason.

## CONCLUSION

In this prospective randomized study it was found that intravenous infusion of paracetamol provides better labour analgesia when given in the active phase of labour as compared to intravenous infusion of tramadol. Maternal adverse effects like nausea, vomiting as well as sedation were found to be associated more with the use of tramadol. So, it can be concluded from our study that intravenous paracetamol may be preferred over intravenous tramadol as it is associated with better analgesic efficacy and less maternal side effects. Although both the drugs were found to have good neonatal outcome.

So, intravenous paracetamol can be used as an alternative to epidural analgesia in developing countries like India where healthcare resources are limited. Further large multicentric studies are required of each drug with placebo as well as intervention groups to have more accurate assessment of efficacy, maternal and fetal side effects and to find a near ideal analgesic in places like India where a cost effective, feasible, safe and efficacious parenteral analgesic is required which does not depend upon skilled care workers or expensive equipments as is required in epidural analgesia.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Jindal S, Goel P, Mitra S, Pandher DK, Rani S. Efficacy and safety of intravenous paracetamol versus intravenous tramadol for labour analgesia. *Int J Reprod Contracept Obstet Gynecol* 2024;13:100-6.