Section: Miscellaneous

Original Research Article

COMPARATIVE EVALUATION OF INTRAVENOUS PARACETAMOL AND INTRAMUSCULAR TRAMADOL FOR LABOUR ANALGESIA IN A TERTIARY CARE CENTRE: A PROSPECTIVE STUDY

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Received *: 10/05/2026*
Received in revised form *: 19/06/2026*
Accepted *: 04/07/2026*

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DOI: 10.70034/ijmedph.2026.3.117

Source of Support: Nil,
Conflict of Interest: None declared

Int J Med Pub Health
2026; 16 (3); 719-724

ABSTRACT

Background: Labour pain is severe and requires effective analgesia to improve maternal comfort and outcomes. Epidural techniques are limited in resource settings, making systemic agents important. Paracetamol and tramadol are commonly used alternatives, but comparative evidence regarding their efficacy and safety remains essential. The objective is to compare the efficacy and safety of intravenous paracetamol and intramuscular tramadol for labour analgesia in term pregnant women by evaluating pain relief, labour progression, maternal adverse effects, maternal satisfaction, and neonatal outcomes, and to identify the more effective and safer analgesic option in a tertiary care setting.

Materials and Methods: This prospective randomized controlled study was conducted at Government Raja Mirasudhar Hospital, Thanjavur, from January to December 2020. A total of 500 primigravida women in active labour were randomized into two groups: intravenous paracetamol (n=250) and intramuscular tramadol (n=250). VAS scores, labour outcomes, maternal adverse effects, and neonatal APGAR scores were assessed and statistically analysed using SPSS.

Results: Participants in both groups had comparable age, gestational age, and baseline pain distribution. After treatment, both paracetamol and tramadol significantly reduced labour pain, with most women reporting mild pain. Normal vaginal delivery was predominant. Neonatal APGAR scores at 1 and 5 minutes were comparable and showed favourable outcomes in both groups.

Conclusion: Both paracetamol and tramadol provide effective labour analgesia with significant reduction in pain scores. Maternal outcomes were comparable with predominance of normal vaginal delivery and no increase in operative interventions. Neonatal APGAR scores were reassuring in both groups. Hence, both drugs are safe and effective options for labour analgesia, and can be used based on clinical setting and requirement.

Keywords: Labour analgesia, Paracetamol, Tramadol, VAS score, APGAR score.

INTRODUCTION

Labour is a physiological process, but it is commonly associated with severe pain and emotional stress. Labour pain is considered one of the most intense forms of pain experienced by women and results from uterine contractions, cervical dilatation, stretching of the birth canal, and pressure on pelvic structures. Inadequately managed labour pain can lead to maternal anxiety, increased catecholamine secretion, hyperventilation, and reduced uteroplacental perfusion, which may

adversely affect both maternal and fetal wellbeing. Therefore, effective labour analgesia has become an important component of modern obstetric care.[1] Over the past few decades, various pharmacological and non-pharmacological methods have been employed to relieve labour pain. Epidural analgesia is widely regarded as the most effective method for labour pain relief; however, its use is often limited in many developing countries, including India, due to the requirement for specialised equipment, trained anaesthesiologists, continuous monitoring, and higher costs. Consequently, systemic analgesics remain a practical and commonly used option in many tertiary care hospitals.[2] Tramadol is a centrally acting synthetic opioid analgesic that acts through weak μ-opioid receptor agonism and inhibition of norepinephrine and serotonin reuptake. Because of its ease of administration, affordability, and relatively favourable safety profile, tramadol has been extensively used for labour analgesia. Several studies have demonstrated that tramadol provides moderate pain relief without significantly affecting the progress of labour. However, its use may be associated with adverse effects such as nausea, vomiting, dizziness, sedation, and occasional neonatal respiratory depression, particularly when administered close to delivery.[3,4] Paracetamol is a non-opioid analgesic and antipyretic agent with established efficacy in the management of acute and postoperative pain. Intravenous paracetamol has gained increasing attention as an alternative labour analgesic because of its rapid onset of action, ease of administration, and excellent maternal and fetal safety profile. Unlike opioid analgesics, paracetamol does not cause respiratory depression, excessive sedation, or significant gastrointestinal side effects. These characteristics make it an attractive option for pain management during labour.[5] Recent evidence suggests that intravenous paracetamol can provide satisfactory analgesia during the active phase of labour while maintaining maternal alertness and ensuring favourable neonatal outcomes. Studies have reported significant reductions in labour pain scores following administration of intravenous paracetamol, with minimal maternal adverse effects. In addition, some investigators have observed better maternal satisfaction and improved tolerance of labour among women receiving paracetamol.[6,7] Direct comparisons between intravenous paracetamol and tramadol have generated considerable interest in recent years. Makkar et al. demonstrated that paracetamol provided effective pain relief comparable to tramadol while producing fewer side effects and better maternal acceptance.[8] Similarly, Lallar et al. reported superior pain relief, shorter labour duration, and fewer adverse effects with intravenous paracetamol compared with intramuscular tramadol.[9] Other studies have also indicated that neonatal outcomes, assessed by APGAR scores and need for neonatal resuscitation, remain comparable between the two drugs, highlighting the safety of both agents when used appropriately during labour.[10] In India, where a large proportion of deliveries occur in busy government and teaching hospitals, there is a continuous need for labour analgesic methods that are effective, safe, inexpensive, and easy to administer. Intravenous paracetamol and intramuscular tramadol fulfil many of these requirements; however, evidence regarding their comparative efficacy and safety remains limited in different populations and healthcare settings. Evaluating these two commonly used analgesics can help obstetricians select the most appropriate pain relief strategy for labouring women. Therefore, the present study was undertaken to compare the efficacy and safety of intravenous paracetamol and intramuscular tramadol as labour analgesics in women undergoing normal labour at a tertiary care centre.

Aim and objective: To compare the efficacy and safety of intravenous paracetamol and intramuscular tramadol for labour analgesia in term pregnant women by evaluating pain relief, labour progression, maternal adverse effects, maternal satisfaction, and neonatal outcomes, and to identify the more effective and safer analgesic option in a tertiary care setting.

MATERIALS AND METHODS

Study design: This was a prospective randomized controlled study.

Study setting: The present study was conducted in the Department of Obstetrics and Gynaecology, Government Raja Mirasudhar Hospital, Thanjavur, Tamil Nadu.

Study duration: The study was carried out over a period of one year from January 2020 to December 2020.

Study population: A total of 500 primigravida women fulfilling the eligibility criteria were enrolled in the study. Participants were randomly allocated into two groups comprising 250 subjects each:

Group A (n = 250): Received intravenous paracetamol.

Group B (n = 250): Received intramuscular tramadol.

Inclusion Criteria:

1. Primigravida women in the active phase of labour.
2. Cervical dilatation ≥ 4 cm.
3. Cervical effacement ≥ 60% with adequate uterine contractions (3–4 contractions per 10 minutes, each lasting approximately 45 seconds).
4. Singleton pregnancy with vertex presentation.
5. Gestational age ≥ 37 completed weeks.
6. Spontaneous onset of labour.
7. Low-risk pregnancy without obstetric or medical comorbidities.

Exclusion Criteria:

1. Clinical evidence of cephalopelvic disproportion.
2. Malpresentation.
3. Multiple pregnancy.
4. Previous uterine scar due to caesarean section or myomectomy.
5. Preterm labour or induced labour.
6. Antepartum haemorrhage.
7. Hypertensive disorders of pregnancy.
8. Known hypersensitivity to paracetamol or tramadol.
9. Significant medical disorders.
10. Fetal distress at admission.
11. Intrauterine fetal demise.
12. Refusal to provide informed consent.

Sampling method: Eligible participants who fulfilled the inclusion and exclusion criteria during the study period were recruited consecutively from the labour ward. After obtaining written informed consent, participants were randomly allocated into two groups using a computer-generated randomization sequence with an allocation ratio of 1:1. Group A received intravenous paracetamol, while Group B received intramuscular tramadol. Randomization was performed to ensure equal distribution of participants and to minimize selection bias between the study groups.

Methods: Institutional Ethics Committee approval was obtained before commencement of the study. Written informed consent was obtained from all participants. A total of 500 eligible primigravida women admitted in active labour were enrolled and randomly assigned into two equal groups.

Group A: Participants received a single dose of intravenous paracetamol (1000 mg in 100 mL solution) administered over 15 minutes.

Group B: Participants received a single intramuscular injection of tramadol hydrochloride 100 mg (2 mL) in the upper outer quadrant of the gluteal region.

Pain intensity was assessed using the Visual Analogue Scale (VAS) before administration of the study drug and subsequently at 1 hour and 3 hours following drug administration. Maternal side effects, labour characteristics, and neonatal outcomes were monitored and recorded.

Visual Analogue Scale (VAS): Pain intensity was graded as follows:

1.0: No pain
2.0.1–3.9: Mild pain
3.4.0–6.9: Moderate pain
4.7.0–10.0: Severe pain

Outcome measures:

The following parameters were evaluated and compared between the two groups:

1. Analgesic efficacy based on VAS scores.
2. Duration of labour.
3. Drug-to-delivery interval.
4. Mode of delivery.
5. Maternal adverse effects.
6. Neonatal outcomes, including APGAR scores and immediate postnatal status.

Statistical analysis: Data were entered into Microsoft Excel and analysed using SPSS software. Continuous variables were expressed as mean ± standard deviation and compared using Student's t-test. Categorical variables were expressed as frequencies and percentages and analysed using the Chi-square test. A p-value of less than 0.05 was considered statistically significant.

Ethical considerations: Prior approval was obtained from the Institutional Ethics Committee before commencement of the study (719/13-01-2020). Written informed consent was obtained from all participants after explaining the study details. Participation was voluntary, and confidentiality of data was maintained throughout the study. The study was conducted in accordance with accepted ethical principles and research guidelines.

RESULTS

Table 1: Age distribution of the participants

Age (In years)	(Group 1) PARACETAMOL	(Group 2) TRAMADOL	P value
	No (%)	No (%)	
11 to 20 years	11 (4.4)	25 (10)	<0.05* (S)
21-30years	238 (95.2)	225 (90)	
31-40 years	1 (0.4)	0	
Total	250	250	
			P value
Mean± S.D	24.2 ±2.4	23.5 ± 2.2	0.02#

Table 2: Gestational age Distribution of the participants

Gestational Age (In weeks)	(Group 1) PARACETAMOL	(Group 2) TRAMADOL	P value
	No (%)	No (%)	
37	67 (26.8)	63 (25.2)	>0.05 (NS)
38	68 (27.2)	67 (26.8)	
39	68 (27.2)	58 (23.2)	
40	47 (18.8)	62 (24.8)	
Total	250	250	
			P value
Mean± S.D	38.3 ±1.07	38.4 ± 1.1	>0.05

Table 3: Distribution of VAS score before Drug Administration

	(Group 1) PARACETAMOL	(Group 2) TRAMADOL	P value
	No (%)	No (%)	
No pain (0-0.5)	0	0	< 0.05*
Mild pain (0.6-4.4)	18 (7.2)	6 (2.4)	
Moderate pain (4.5-7.4)	110 (44)	115(46)	
Severe pain (7.5- 10)	122 (48.8)	129 (51.6)	
Total	250	250	

Table 4: Mean Vas Score before Drug Administration

	Group 1	Group 2	P value
	Mean ± SD	Mean ± SD	
VAS score	7.22 ± 2.2	6.46 ±1.85	<0.05* (S)

Table 5: Mean Vas Score after 1hr Administration

	Group 1	Group 2	P value
	Mean ± SD	Mean ± SD	
VAS score	7.55 ± 1.91	8.1 ±1.8	<0.05*

Table 6: Mean Vas Score after 3hr Administration

	Group 1	Group 2	P value
	Mean ± SD	Mean ± SD	
VAS score	3.83 ± 2.1	2.92 ±2.39	<0.05*

Table 7: Mean Duration of 1st Stage of Labor

	Group 1	Group 2	P value
	Mean ± SD	Mean ± SD	
Duration	218.6 ± 18.4	283.5 ± 26.85	<0.05*

Table 8: Mean Duration of 2nd Stage of Labor

	Group 1	Group 2	P value
	Mean ± SD	Mean ± SD	
Duration	32.5 ± 2.33	39.32 ±2.8	<0.05*

Table 9: Mean Duration of 3rd Stage of Labor

	Group 1	Group 2	P value
	Mean ± SD	Mean ± SD	
Duration	7 ± 1.4	9.6 ±1.6	< 0.05*

Table 10: Distribution of Patient Satisfaction

	(Group 1) PARACETAMOL	(Group 2) TRAMADOL
	No (%)	No (%)
Good	250 (100)	250 (100)

Most participants were aged 21–30 years in both the paracetamol (95.2%) and tramadol (90.0%) groups. The mean ages were comparable (24.2 ± 2.4 vs. 23.5 ± 2.2 years), indicating similar baseline age distribution [Table 1]. Most participants had a gestational age of 38 weeks in both the paracetamol (27.2%) and tramadol (26.8%) groups. The mean gestational ages were comparable (38.3 ± 1.07 vs. 38.4 ± 1.10 weeks), indicating similar baseline characteristics. [Table 2]. Before drug administration, most participants experienced severe pain, observed in 48.8% of the paracetamol group and 51.6% of the tramadol group. Moderate and mild pain distributions were also comparable between the two groups [Table 3]. According to the VAS score, severe pain was reported by 53.2% of participants in the paracetamol group and 77.2% in the tramadol group. Moderate and mild pain were less frequent, with a higher proportion of moderate pain observed in the paracetamol group [Table 4]. Following treatment, most participants reported mild pain on the VAS in both the paracetamol (65.6%) and tramadol (64.8%) groups, with few experiencing severe pain. Normal vaginal delivery was the predominant mode of delivery in both groups (94.8% vs. 92.8%), indicating comparable obstetric outcomes [Table 5-10]. At 1 minute, 98.8% of neonates in the paracetamol group and 98.4% in the tramadol group had an APGAR score >7, while 1.2% and 1.6%, respectively, had scores ≤6. At 5 minutes, APGAR scores ≥9 were observed in 89.2% and 96% of neonates in the paracetamol and tramadol groups, respectively, whereas scores ≤8 were seen in 10.8% and 4%, respectively.

DISCUSSION

The present study compared the efficacy and safety of paracetamol and tramadol for labour analgesia with respect to pain relief, mode of delivery, and

neonatal outcomes. Overall, both groups were comparable at baseline with respect to age and gestational age distribution, thereby reducing potential confounding factors influencing outcomes. In the present study, prior to drug administration, a comparable proportion of women in both groups experienced moderate to severe pain, indicating similar baseline labour pain perception. After administration of analgesics, a marked reduction in pain intensity was observed in both groups, with a higher proportion of women reporting mild pain. This indicates that both paracetamol and tramadol are effective in providing labour analgesia. However, a relatively higher proportion of severe pain persisted in the tramadol group compared to paracetamol group in some observations, suggesting a possible variability in analgesic response and onset of action between the two drugs. Paracetamol acts centrally by inhibiting prostaglandin synthesis and modulating serotonergic pathways, thereby reducing pain perception without significant respiratory depression or sedation. Tramadol, on the other hand, acts as a weak μ-opioid receptor agonist and also inhibits reuptake of serotonin and noradrenaline, which contributes to its analgesic effect. Although tramadol is generally considered a stronger analgesic, its efficacy in labour pain relief may be influenced by inter-individual variability, maternal anxiety, and pharmacogenetic differences affecting metabolism. In the present study, the majority of women in both groups had normal vaginal delivery, with a small proportion undergoing caesarean section (LSCS) and instrumental delivery. This indicates that neither paracetamol nor tramadol adversely affected labour progression or increased operative delivery rates. Similar findings have been reported in previous studies where non-epidural analgesic agents did not significantly alter the mode of delivery when used judiciously during labour pain management.[11-13] The neonatal outcomes assessed using APGAR scores at 1 and 5 minutes were reassuring in both groups. At 1 minute, nearly all neonates in both groups had APGAR scores greater than 7, indicating good immediate neonatal adaptation. At 5 minutes, a higher proportion of neonates achieved APGAR scores ≥9 in the tramadol group compared to the paracetamol group, although both groups demonstrated overall favourable outcomes. The proportion of neonates with lower APGAR scores remained minimal and comparable between groups. These findings suggest that both drugs are relatively safe for neonatal outcomes when used in appropriate doses during labour. Tramadol, although an opioid-related drug, did not demonstrate significant neonatal respiratory depression or poor adaptation in the present study. This is consistent with earlier studies reporting minimal neonatal adverse effects when tramadol is used in controlled obstetric settings.[14-22] The comparable APGAR scores between the two groups further reinforce that neither drug adversely affects uteroplacental perfusion or fetal well-being when administered during active labour. Paracetamol, due to its favourable safety profile and minimal placental transfer effects, continues to be considered a safe option in labour analgesia. However, tramadol remains a useful alternative, particularly in settings where stronger analgesia is required and epidural services are not available. Overall, the present study highlights that both paracetamol and tramadol are effective and safe options for labour analgesia. While tramadol may offer slightly stronger analgesic potential in some cases, paracetamol provides comparable pain relief with an excellent safety profile. The choice of agent may therefore depend on clinical setting, patient characteristics, and availability of monitoring facilities. Further large-scale randomized controlled trials are required to establish definitive superiority between these agents and to optimise dosing regimens for labour analgesia while ensuring maternal comfort and neonatal safety.

CONCLUSION

Both paracetamol and tramadol were found to be effective for labour analgesia with significant reduction in pain scores and acceptable maternal comfort. The majority of women in both groups had favourable labour outcomes with a predominance of normal vaginal delivery and no significant increase in operative delivery rates. Neonatal outcomes assessed by APGAR scores at 1 and 5 minutes were comparable and reassuring in both groups, indicating good safety profile for the newborn. Overall, both drugs can be considered safe and effective options for labour analgesia, with choice of drug depending on clinical setting, patient condition, and availability of monitoring facilities.

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