

# Comparative Analysis of Intravenous Paracetamol and Tramadol for Labor Analgesia: Efficacy and Safety

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## ABSTRACT

**Objective:** This study aims to compare the efficacy and safety of intravenous paracetamol and intramuscular tramadol for labor analgesia.

**Study Design and Setting:** This study was conducted for 1 year at PNS Shifa Hospital, Karachi (Sept 01, 2023 – Aug 31, 2024). Convenient sampling into two groups was done (Group A: IV Paracetamol n=50; and Group B: IM Tramadol n=50) of 100 laboring women. Visual Analogue Scale was used to assess pain intensity at baseline, 1 and 3 hours post administration.

**Methodology:** During the active phase of labor, participants were given either 1,000 mg IV paracetamol or 100 mg IM tramadol. Labor progression was monitored and the levels of pain were recorded on the VAS. Statistical tests were used to analyze maternal side effects and neonatal outcomes such as NICU admissions with a significance threshold of  $p < 0.05$ .

**Results:** Superior pain relief was given by paracetamol with significantly lower VAS scores at 1 hour (4.44 vs. 5.55,  $p = 0.0$ ) and 3 hours (6.51 vs. 6.96,  $p = 0.0$ ). In the paracetamol group, labor duration of paracetamol group was shorter in the first stage (10.16 vs. 11.44 hours,  $p = 0$ ). The number of frequent maternal side effects was higher in the tramadol group (24 vs 12%,  $p = 0.118$ ). Furthermore, there was no difference in NICU admissions or emergency cesarean rates ( $p = 0.315$ ).

**Conclusion:** Intravenous paracetamol is a safer and better alternative for labor analgesia as compared to intramuscular tramadol, having better pain control, shorter duration of labor and less maternal side effects and similar neonatal outcomes.

**Keywords:** Labor analgesia, maternal outcomes, Pain management, Paracetamol, Tramadol.

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## INTRODUCTION:

Labor pain is considered one of the most intense forms of pain that women experience,<sup>1</sup> often compared to other severe physiologic causes of pain, such as complex regional pain syndromes (CRPS) or finger amputation.<sup>2-5</sup> For many women, labor pain is the most extreme discomfort they will face during their reproductive years, frequently accompanied by intense emotional responses such as anxiety, fear, and feelings of insecurity. These negative emotions can sometimes drive women to opt for a caesarean section in order to avoid the pain associated with labor.<sup>5</sup>

Labor pain, primarily due to uterine contractions,<sup>6</sup> is a natural part of childbirth. However, both anticipation and experience of this pain can cause concern, especially in first-time mothers (primiparous), who often feel heightened anxiety and fear. The pain's intensity is subjective, influenced by factors like contraction strength and frequency, cervical dilation rate, and parity, or number of prior births.<sup>1</sup> A woman's reaction to childbirth pain is shaped by her individual circumstances, including pain threshold, past delivery experiences, coping mechanisms, and pain intensity. Cultural factors also play a significant role, with some cultures favoring medical pain relief, like epidurals, while others view enduring

labor pain as a symbol of courage or a rite of passage. These personal, cultural, and medical influences significantly affect women's choices regarding pain management.<sup>7</sup>

As a result of the fact that the management of labor pain is dependent on the preferences of the individual, their prior experiences, and the cultural milieu in which they practice, medical professionals are required to take into consideration the aforementioned factors while providing opportunities for pain treatment and assistance during the delivery process.<sup>7</sup>

Labor analgesia can be broadly classified into non-pharmacological and pharmacological methods. Non-pharmacological approaches include transcutaneous electrical nerve stimulation (TENS), continuous labor support, touch and massage, water baths, intradermal sterile water injections, acupuncture, and hypnosis. These methods provide alternative pain relief without medication but may not always be sufficient for severe labor pain. On the other hand, pharmacological techniques include the use of parenteral opioids, opioid antagonists, inhalational agents, and regional analgesia.<sup>8</sup> Among these, regional analgesia is considered the gold standard for labor pain relief. However, it requires specialized equipment, continuous monitoring, and a 24-hour anesthetic service, which may not be feasible in resource-limited settings, especially in developing countries like Pakistan.

For labor analgesia, intramuscular (IM) tramadol and intravenous (IV) paracetamol are both viable options that may be used in situations when sophisticated aesthetic treatments might not be easily accessible. The fact that these drugs are widely available, require just a small amount of technical competence, and are reasonably affordable makes them ideal alternatives for controlling labor pain in circumstances like these.<sup>8</sup>

Tramadol is a synthetic opioid that functions similarly to pethidine, with a moderate affinity for mu-opioid receptors.<sup>9</sup> The analgesic action begins within 10 minutes after intramuscular injection and lasts for 2 to 3 hours. Prior evidence indicated that tramadol serves as an effective analgesic during labor, devoid of the maternal or newborn respiratory depression risks often linked to other opioids. Moreover, tramadol does not hinder stomach emptying, a common issue associated with opioid administration during childbirth.<sup>10</sup>

In contrast, paracetamol is a famous antipyretic and non-narcotic analgesic that has fewer adverse effects.<sup>1</sup> Its peripheral activities that prevent the production of pain impulses and its central nervous system inhibition of prostaglandin synthesis are what make it effective in relieving pain. Some researchers think that cannabinoid receptor agonism and serotonergic pathways contribute to its analgesic effects. Because of these effects, intravenous paracetamol is a promising substitute for opioids as a labor analgesic.<sup>1</sup>

In light of these considerations, we decided to carry out this

research in order to evaluate the effectiveness and safety of intramuscular tramadol and intravenous paracetamol as they pertain to labor analgesics. In environments where there is a restricted availability of sophisticated anesthetic resources, our objective was to locate the most effective method for the treatment of labor pain.

#### **METHODOLOGY:**

The study was conducted over a period of one year from Sept 01, 2023 - Aug 31, 2024, at Gynae/Obs deptt of PNS Shifa hospital Karachi being a Quasi experimental study. The research stands under ERC # 132 and was approved by ethical review committee of the hospital. The objective of the study was to evaluate the analgesic efficacy and safety of intravenous (IV) paracetamol compared with intramuscular (IM) tramadol in the management of labor pain.

One hundred parturients meeting the inclusion criteria were enrolled and divided in two groups by convenient sampling technique. Group A (n = 50): Received 1,000 mg of IV paracetamol over a 15-minute infusion during the active phase of labor. Group B consisted of 50 women and received 0.1 g IM tramadol in a single dose at the same stage of labor.

**Inclusion Criteria:** Singleton pregnancy. The demo population was primigravida or multigravida women aged 18–40 years. Full-term pregnancy (37–42 weeks gestation). In active labor with cervical dilation =4 cm and regular contractions. No contraindications to vaginal delivery or analgesia.

**Exclusion Criteria:** History of hypersensitivity to paracetamol or tramadol. Illnesses to the mother, such as preeclampsia, eclampsia, cardiovascular conditions. Multiple gestations or known fetal anomalies.

Other analgesics used within 24 hours before the study. Contraindications on the labor analgesia (such as clotting disease, injection site infection). **Outcome Measures:** Primary Outcome: The pain severity was assessed by Visual Analogue Scale (VAS); (0 = no pain, 10 = worst pain).

Baseline (before drug administration). 1 hour after administration. 3 hours after administration **Secondary Outcomes:** Cervical dilation progression. Time duration of first and second stages of labor. Nauseas, vomitus, drowsyess, allergic reactions. Apgar scores at 1 and 5 minutes and NICU admissions are neonatal outcomes.

**Data Collection and Analysis:** Labor and delivery doctors and nurses used standardized forms using convenient sampling to collect data. IBM SPSS (version 22.0) was used for statistical analysis.

VAS scores, duration of labour and cervical dilation were compared by use of independent t tests.

Categorical variables (maternal side effects, neonatal outcomes) were analyzed by means of Chi-square tests.

Statistical significance was defined as a p less than 0.05.

Institutional review board ethical approval and informed

written consent before enrollment was obtained for all participants.

#### Outcome Measures

**Primary Outcome:** Pain Severity was the primary outcome of this study, measured using the Visual Analogue Scale (VAS). The VAS is a 10-point scale, where 0 represents "no pain" and 10 represents the "worst possible pain." This scale was selected due to its widespread use in clinical pain assessments and its ability to quantify subjective pain intensity.

Pain intensity was measured at three key time points:

- **Baseline (before drug administration):** Pain levels were assessed to ensure that both groups had comparable pain intensity at the start of the intervention.
- **1 hour post-drug administration:** This time point was selected to assess the short-term analgesic effect of both drugs.
- **3 hours post-drug administration:** This time point was chosen to evaluate the sustained efficacy of each analgesic over time.
- **All pain assessments were conducted by a designated doctor who was blinded to the treatment groups.** The doctor/nurse recorded VAS scores for each participant, ensuring consistency in data collection.
- **Secondary Outcomes** In addition to pain relief, secondary outcomes included:
  - **Cervical Dilatation:** The progression of labor was monitored by measuring cervical dilatation at baseline and every hour thereafter. Cervical dilatation was recorded in centimeters to assess whether analgesia had any impact on labor progression. It was hypothesized that effective pain relief could potentially shorten labor by reducing maternal stress and allowing for better cooperation during the labor process.
  - **Duration of Labor:** The total duration of labor was recorded for each participant, from the active phase until delivery. Labor duration was divided into two stages:
    - **First stage of labor:** Defined as the time from the onset of regular contractions with cervical dilatation of 4 cm to full dilatation (10 cm).
    - **Second stage of labor:** Defined as the time from full cervical dilatation to the delivery of the neonate.
  - **Maternal Side Effects:** Maternal safety was closely monitored, with adverse effects such as nausea, vomiting, disorientation, and allergic reactions recorded immediately after medication administration and during later labor stages. Side effects were categorized as mild, moderate, or severe, with prompt treatment provided as needed.

- **Neonatal Outcomes:** Neonatal well-being was assessed through 1- and 5-minute Apgar scores, evaluating heart rate, breathing, muscle tone, reflexes, and skin color. NICU admissions were documented to gauge the analgesics' safety for newborns, with any adverse neonatal outcomes carefully observed.

**Data Collection and Management:** Data was collected by qualified labor and delivery doctor and nurses who were unaware of the treatment groups to reduce bias. The drugs used were chosen because of their easy availability in abundance in the hospital. Pain ratings, cervical dilation, and maternal side effects were documented using standardized data collecting forms. Neonatal outcomes, like Apgar scores and NICU hospitalizations, were recorded immediately post-delivery. All gathered data were inputted into a secure, password-protected database to maintain confidentiality. Access to the data was restricted to authorized people, and each participant was granted a unique identity number to ensure anonymity. Data verification and cleansing were conducted before analysis to guarantee precision. Verification and cleansing were conducted prior to analysis to guarantee precision.

Data analysis was conducted using IBM SPSS version 22.0. Descriptive statistics, including means, standard deviations, and frequencies, summarized the demographic and clinical characteristics of the participants. For comparing continuous variables like VAS ratings, cervical dilation, and labor duration between the groups at specific time points, independent t-tests were used. Categorical variables such as maternal side effects, Apgar scores, and NICU admissions were analyzed with chi-square tests. A p-value of less than 0.05 was considered statistically significant in all analyses.

#### RESULTS:

The table 1 compares the effects of paracetamol and tramadol for labor analgesia. Both groups had similar baseline characteristics in age, gestational age, BMI, cervical dilation, and initial pain scores, with no significant differences observed. However, at 1 and 3 hours post-treatment, paracetamol provided significantly better pain relief (VAS scores of 4.44 and 6.51) compared to tramadol (VAS scores of 5.55 and 6.96). Paracetamol was also associated with shorter labor durations, including the first stage (10.16 vs. 11.44 hours), active phase of the first stage (4.18 vs. 5.06 hours), and second stage (34.04 vs. 37.66 minutes), all with significant p-values ( $p = 0.0$ ), indicating its superior efficacy in both pain management and labor progression.

In Table 2, outcomes such as NICU admissions, maternal side effects, and emergency cesarean sections were also compared between the groups. NICU admissions were minimal, with only 1 admission from the Paracetamol group (2.0%) and none from the Tramadol group, resulting in a 1.0% NICU admission rate overall. The p-value of 0.315

indicates no statistically significant difference between the groups regarding NICU admissions. Maternal side effects were reported more frequently in the Tramadol group (24%) than in the Paracetamol group (12%), but this difference

was not statistically significant ( $p = 0.118$ ). Emergency cesarean sections were rare, with only 1 case in the Paracetamol group (2.0%) and none in the Tramadol group, with a  $p$ -value of 0.315 indicating no significant difference.

Table 1: Continuous variables of the study

Variable	Group	Mean	Standard Deviation	p-value
Age(years)	Paracetamol	25.82	2.24	0.907
	Tramadol	25.22	2.25	
Gestational Age(weeks)	Paracetamol	39.07	0.26	0.342
	Tramadol	38.96	0.28	
Pre-pregnancy BMI	Paracetamol	23.28	0.44	0.191
	Tramadol	23.20	0.39	
Cervical Dilatation	Paracetamol	4.74	0.38	0.112
	Tramadol	4.87	0.42	
VAS Before Treatment	Paracetamol	8.54	0.54	0.708
	Tramadol	8.59	0.62	
VAS 1 hr After Treatment	Paracetamol	4.44	0.27	0.0
	Tramadol	5.55	0.30	
VAS 3 hr After Treatment	Paracetamol	6.51	0.33	0.0
	Tramadol	6.96	0.30	
Duration 1st stage (hours)	Paracetamol	10.16	0.95	0.0
	Tramadol	11.44	1.25	
Duration of active phase of first stage of labour(hours)	Paracetamol	4.18	0.85	0.0
	Tramadol	5.06	0.74	
Duration of 2nd stage (minutes)	Paracetamol	34.04	1.47	0.0
	Tramadol	37.66	1.73	

Table 2: Comparison of side effects of the drugs

Variables		Group			P value
		Paracetamol	Tramadol	Total	
NICU admission	Yes	1	0	1	0.315
		2.0%	0.0%	1.0%	
	No	49	50	99	
		98.0%	100.0%	99.0%	
Maternal side effects	Yes	6	12	18	0.118
		12%	24%	18%	
	No	44	38	82	
		88%	76%	82%	
Emergency cesarean section	Yes	1	0	1	0.315
		2.0%	0	2.0%	
	No	49	50	99	
		98.0%	1000%	99.0%	

**DISCUSSION:**

Pain management during labor remains a critical aspect of obstetric care, aiming to enhance maternal comfort while minimizing adverse effects on both the mother and neonate. As labor pain is often described as one of the most severe forms of pain, adequate analgesia can significantly improve

the childbirth experience. Our study aimed to compare the analgesic efficacy and safety profiles of intravenous (IV) paracetamol and intramuscular (IM) tramadol during labor. These findings are supported by studies conducted by N Monisha et al,<sup>11</sup> Meenakshi Lallar,<sup>12</sup> and a comparative study involving primigravidae labor patients. Together, the evidence

strongly suggests that IV paracetamol is superior to IM tramadol in labor analgesia, offering prolonged pain relief, fewer maternal side effects, and improved labor progression.

In our study, the use of IV paracetamol demonstrated significantly better pain control compared to IM tramadol, as measured by the Visual Analog Scale (VAS) scores at 1 hour and 3 hours post-administration. The paracetamol group had a VAS score of 4.44 at 1 hour and 6.51 at 3 hours, compared to 5.55 and 6.96 for the tramadol group, with both differences being highly significant ( $p = 0.0$ ). These findings align with the results of N Monisha et al.<sup>11</sup>

At 3 hours post-administration, Lallar<sup>12</sup> found that while 26% of women in the paracetamol group continued to experience "distressing" pain, 51% of women in the tramadol group still reported "horrible" pain. This marked difference emphasizes the longer duration of action and superior pain control offered by IV paracetamol compared to IM tramadol. Both our study and the referenced studies corroborate that IV paracetamol has a more sustained analgesic effect, significantly reducing the intensity of labor pain for a longer period compared to tramadol.

The ability of paracetamol to shorten labor duration can be particularly beneficial in reducing maternal exhaustion and improving overall labor outcomes. Tramadol, while effective to some extent, does not seem to offer the same advantages in labor progression. The longer duration of labor observed in the tramadol group across studies could be attributed to less effective pain relief, leading to heightened maternal discomfort and slower cervical dilation, which may contribute to prolonged labor stages.

Our results, together with those of N Monisha et al,<sup>11</sup> Meenakshi Lallar<sup>12</sup> and the comparison analysis<sup>5,7</sup> all point to important directions for future research and patient care. It seems that intravenous paracetamol is a very efficient analgesic for labor, with advantages over intramuscular tramadol such as shorter labor length, less maternal adverse effects, and better pain alleviation.<sup>15</sup> The benefits listed above make intravenous paracetamol the drug of choice for labor analgesia, particularly when the mother's comfort and safety are paramount and long-term analgesia is necessary.

Further, our findings align with those of Sania Jindal<sup>16</sup> who compared intravenous paracetamol (1000 mg) and tramadol (1 mg/kg) for labor analgesia in parturients at 4-6cm cervical dilation. In her study, baseline pain scores were similar between groups, but at 1 hour, the Visual Analog Scale (VAS) score was significantly lower in the paracetamol group (4.60) than in the tramadol group (5.82), mirroring our results. By 3 hours, VAS scores were slightly lower for paracetamol (6.35) compared to tramadol (6.65), though the difference was not statistically significant. The incidence of side effects such as nausea, vomiting, and sedation was notably higher in the tramadol group ( $n=13$ ) than in the paracetamol group ( $n=3$ ), consistent with findings by Makkar

et al<sup>17</sup> who observed more frequent sedation in tramadol-treated patients. Additionally, neonatal outcomes, assessed by 1- and 5-minute Apgar scores, were comparable between groups, suggesting both drugs are safe for neonatal health.

Similarly, Elbohoty et al<sup>18</sup> found paracetamol to be as effective as pethidine for labor analgesia, with only a brief period at 15 minutes where pethidine offered superior pain relief ( $p = 0.004$ ). Beyond this time, there was no notable difference in analgesic effect. Regarding labor duration, Jindal observed no significant difference between paracetamol and tramadol, aligning with Aimakhu et al's<sup>19</sup> results comparing intramuscular paracetamol (600 mg) and tramadol (100 mg). Together, these studies indicate that intravenous paracetamol not only offers effective and prolonged pain relief but also maintains a favorable side effect profile, reinforcing its potential as a preferred labor analgesic.

Paracetamol administered intravenously has a positive safety profile and may be used during pregnancy to reduce the need for intense monitoring of both the mother and the fetus.<sup>20</sup> Its low effect on neonatal outcomes further supports this recommendation. Overall labor outcomes and the need for interventions like emergency cesarean sections may be improved if intravenous paracetamol were to be used more often, according to the data.<sup>21</sup>

In conclusion, our research, in conjunction with other studies indicates that intravenous paracetamol provides enhanced analgesia, a more advantageous safety profile, and reduced labor length relative to intramuscular tramadol. The uniform results from these trials underscore the efficacy and safety of IV paracetamol as an analgesic during labor. Additional extensive studies are necessary to further validate these findings and investigate further advantages of IV paracetamol in labor analgesia; nonetheless, the existing data robustly supports its use as a primary analgesic in obstetric care.

## CONCLUSION

The results of this study indicate that intravenous (IV) paracetamol is more effective and less harmful as a labor analgesia than intramuscular (IM) tramadol. There was superior pain relief following IV paracetamol based on significantly lower Visual Analogue Scale (VAS) scores at one hour and three hours after administration. Also, labor duration was significantly shorter in newborns of the paracetamol group, indicating that efficient pain control could lead to faster labor progression.

Future research should consist of larger multi-center trials and comparisons with other analgesic options as well as long term maternal and neonatal outcomes. IV paracetamol is an attractive, non-opioid option to manage pain as it provides safe, effective, pain relief for labour without endangering neonatal safety.

**Authors Contribution:**  
**Naila Mushtaq:** Manuscript writing, data analysis, final approval  
**Ayesha Arif:** Manuscript editing, final approval  
**Shazia Iffet:** Data analysis, proof reading  
**Sadaf Moin:** Statistical review, data analysis  
**Tahira Parveen:** Data collection, proof reading  
**Qosain Suriya:** Manuscript writing, statistical review

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