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Original Research Article

Efficacy and safety of intravenous paracetamol versus intramuscular tramadol for labor analgesia: a randomized controlled trial

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ABSTRACT

Background: Effective labor analgesia should relieve pain without compromising maternal or neonatal safety. This study compared intravenous paracetamol with intramuscular tramadol for analgesia during active labor.
Methods: This prospective, open-label, randomized controlled trial was conducted at Dr. Rajendra Prasad Government Medical College, Kangra at Tanda, Himachal Pradesh, from July 2024 to June 2026. Of 156 women assessed for eligibility, 153 were randomized to intravenous paracetamol 1 g (n=77) or intramuscular tramadol 100 mg (n=76); 150 were included in the final analysis. Pain was assessed using a 10-cm visual analogue scale before treatment and at 1, 2, and 3 hours. Labor duration, drug-to-delivery interval, maternal adverse effects, and neonatal outcomes were assessed.
Results: Mean visual analogue scale (VAS) scores were lower with paracetamol at 1, 2, and 3 hours (4.31±0.50 versus 6.35±0.65; 4.15±0.43 versus 6.53±0.62; and 4.99±0.71 versus 6.59±0.64; all p<0.0001). First- and second-stage labor duration and drug-to-delivery interval were shorter with paracetamol (all p<0.001). Nausea/vomiting and drowsiness were less frequent with paracetamol (1.3% versus 12.0%, p=0.0088; 0% versus 9.3%, p=0.0067). Birth weight and 1-minute Apgar scores were comparable, while 5-minute Apgar score ≥9 was more frequent with paracetamol (97.3% versus 78.7%; p=0.0004). NICU admission was comparable (2.7% versus 6.7%; p=0.245).
Conclusions: Intravenous paracetamol provided greater pain reduction and fewer maternal adverse effects than intramuscular tramadol during active labor. The association with shorter labor duration should be interpreted cautiously because of baseline obstetric differences.

Keywords: Labor analgesia, Paracetamol, Tramadol, Visual analogue scale, Maternal outcome, Neonatal outcome

INTRODUCTION

Labor is a physiological process characterized by regular uterine contractions and progressive cervical dilatation, but it is frequently associated with severe pain. The intensity and perception of labor pain vary considerably among women and are influenced by physiological, psychological, emotional, and social factors. Pain during labor is not only a distressing experience but may also produce substantial maternal physiological responses, including increased sympathetic activity, oxygen consumption, and neuroendocrine stress. These responses may affect maternal comfort and the course of labor, emphasizing the importance of effective and safe intrapartum analgesia.[1,2]

Neuraxial analgesia, particularly epidural analgesia, provides effective pain relief during labor and remains an important modality of obstetric analgesia. However, its availability may be limited in many healthcare settings because it requires trained personnel, specialized equipment, continuous monitoring, and appropriate infrastructure.[3] These limitations are particularly relevant in resource-constrained settings, where simpler, inexpensive, and readily administered pharmacological alternatives may be required. Consequently, systemic analgesics continue to have an important role in providing

pain relief to women who cannot access or do not prefer neuraxial analgesia.[4]

Paracetamol is a non-opioid analgesic with established analgesic and antipyretic properties and has increasingly been investigated for intrapartum analgesia. Its established safety profile, ease of administration, and applicability in the perinatal period have generated interest in its intravenous use during labor.[5,6] Intravenous paracetamol has been evaluated in several studies as an alternative systemic analgesic during labor, with evidence suggesting meaningful reduction in pain intensity and a favorable maternal safety profile.[7,8]

Tramadol is a centrally acting analgesic with weak μ-opioid receptor agonist activity and additional effects on serotonin and norepinephrine reuptake. It has been used as a parenteral analgesic during labor because of its relative ease of administration and availability. However, opioid analgesics may be associated with maternal adverse effects such as nausea, vomiting, dizziness, and drowsiness.[9] In addition, the placental transfer of tramadol and potential neonatal effects are important considerations when selecting an analgesic during labor.[10]

Several comparative studies have evaluated intravenous paracetamol and intramuscular tramadol for labor analgesia, but their findings have not been entirely uniform. Makkar et al reported comparable analgesic efficacy between paracetamol and tramadol during active labor, although the duration of the first stage of labor was shorter with paracetamol and maternal adverse effects were more frequent with tramadol.[11] Lallar et al reported greater reduction in pain intensity with intravenous paracetamol and a shorter duration of labor, with nausea and vomiting occurring more frequently in women receiving tramadol.[12] Similar findings were reported by Mohan et al who observed greater pain relief, shorter labor duration, and fewer maternal adverse effects with intravenous paracetamol compared with intramuscular tramadol.[13] Das et al also reported significantly lower pain scores and shorter labor duration with intravenous paracetamol.[11]

More recent clinical evidence has continued to support the potential role of intravenous paracetamol for labor analgesia. Marwah et al reported better pain relief with intravenous paracetamol compared with tramadol, while studies evaluating paracetamol in low-resource settings have also demonstrated its efficacy and safety for management of labor pain.[1] A randomized controlled trial by Monisha et al comparing intravenous paracetamol with intramuscular tramadol similarly reported greater and more sustained pain reduction with paracetamol, together with fewer maternal adverse effects.[2] However, differences among studies in patient characteristics, timing of analgesic administration, pain assessment methods, and evaluation of maternal and neonatal outcomes highlight the need for further well-designed randomized comparative studies.

Therefore, the present randomized controlled trial was undertaken to compare the analgesic efficacy and safety of intravenous paracetamol with intramuscular tramadol in women in active labor. The primary objective was to compare pain intensity using the visual analogue scale before administration and at 1, 2, and 3 hours after administration of the respective analgesic. The secondary objectives were to compare the duration of labor, maternal adverse effects, and neonatal outcomes between the two treatment groups.

METHODS

Study design and setting

The study was a hospital-based, prospective, open-label, two-arm, parallel-group randomized controlled trial conducted in the Department of Obstetrics and Gynecology, Dr. Rajendra Prasad Government Medical College, Kangra at Tanda, a multispecialty tertiary healthcare facility located in the Kangra valley of Himachal Pradesh, India.

Study duration

The study was conducted from July 2024 to June 2026.

Study population

Pregnant women admitted to the labor room who fulfilled the prespecified eligibility criteria were assessed for participation. Women were enrolled after obtaining written informed consent.

Sample size

The sample size was calculated using previously reported proportions of analgesic efficacy of 38.18% with intravenous paracetamol and 16.36% with intramuscular tramadol. With α=0.05, 80% power, and a 1:1 allocation ratio, the required sample size was approximately 65 participants per group. Allowing for 10% attrition required approximately 73 participants per group; this was rounded to 75 per group. Thus, the planned sample size was 150 participants (75 in each group).

Inclusion criteria

Pregnant women in early/active labor with a singleton pregnancy and cephalic presentation who fulfilled the prespecified eligibility criteria were included. Participants were enrolled after obtaining written informed consent.

Exclusion criteria

Women with clinical evidence of cephalopelvic disproportion, severe pre-eclampsia, diabetes mellitus, a previously scarred uterus, malpresentation (breech presentation), fetal distress, or antepartum hemorrhage were excluded. Women who subsequently underwent

emergency cesarean section during labor were also excluded from the final analysis.

Randomization and allocation

Participants who fulfilled the eligibility criteria and provided written informed consent were randomized in an approximately 1:1 ratio into two parallel treatment groups using a computer-generated random allocation sequence prepared by the principal investigator. A total of 153 participants were randomized, with 77 participants allocated to group P (paracetamol) and 76 to group T (tramadol). Allocation concealment was maintained using sequentially numbered, opaque, sealed envelopes, each containing a slip indicating either injection paracetamol or injection tramadol. Each participant selected an envelope without opening it, after which the treatment allocation was revealed and recorded by the principal investigator. Participants were unaware of the treatment allocation before selection of the envelope. Women allocated to group P received intravenous paracetamol, whereas those allocated to group T received intramuscular tramadol. During follow-up, 2 participants in group P and 1 participant in group T underwent emergency cesarean delivery. As the prespecified labor analgesia outcomes could no longer be assessed as planned after emergency cesarean delivery, these 3 participants were excluded from the final labor-analgesia analysis. Thus, 75 participants in each group were included in the final analysis. Owing to the different routes of administration of the two interventions, blinding of participants and treating clinicians was not feasible.

Study procedure

At admission, detailed personal, medical, menstrual, and obstetric histories were obtained, followed by general, systemic, and obstetric examinations, including abdominal, speculum, and vaginal examinations. Routine investigations were performed according to the institutional labor-room protocol. Baseline maternal and obstetric characteristics were recorded before administration of the study intervention.

Participants randomized to group P received injection paracetamol 1 g (manufactured by Fresenius Kabi India Pvt. Ltd., Pune, Maharashtra, India) intravenously as an infusion over 10 minutes during labor when cervical dilatation was >3 cm.

Participants randomized to group T received injection tramadol 100 mg (manufactured by Supermax Drugs and Pharmaceuticals Pvt. Ltd., Narela, Delhi, India) intramuscularly during labor when cervical dilatation was >3 cm.

Measurement of outcomes

Pain intensity was assessed using a 10-cm visual analogue scale (VAS), with 0 representing no pain and 10 representing maximum pain. VAS scores were recorded immediately before administration of the study drug and at 1, 2, and 3 hours thereafter. The primary outcome was pain intensity measured by VAS at the prespecified time points. Secondary outcomes included duration of labor, interval from drug administration to delivery, maternal adverse effects, and neonatal outcomes. Maternal adverse effects were assessed during labor and for 24 hours after delivery, while neonatal outcomes included birth weight, Apgar scores, and NICU admission. Maternal and neonatal outcomes were recorded according to the labor-room protocol. Labor progression was monitored using the WHO-modified partograph, and the study drug was administered when cervical dilatation was >3 cm.

Statistical analysis

Data were collected, cleaned, and entered into Microsoft Excel and analyzed using IBM statistical package for the social sciences (SPSS) statistics version 27.0 and GraphPad Prism version 5.0. Continuous variables were summarized as mean and standard deviation, while categorical variables were presented as frequencies and percentages. The normality of continuous variables was assessed using the Shapiro-Wilk test. Between-group comparisons were performed using the independent student's t-test for normally distributed continuous variables and the Mann-Whitney U test for non-normally distributed variables. Categorical variables were compared using the Chi-square test or Fisher's exact test, as appropriate. All tests were two-tailed, and a p value <0.05 was considered statistically significant.

RESULTS

A total of 156 women were assessed for eligibility; 3 were excluded because they did not meet the eligibility criteria. The remaining 153 women were randomized, with 77 allocated to group P (paracetamol) and 76 to group T (tramadol). During the study, 2 participants in group P and 1 participant in group T underwent emergency cesarean delivery and were excluded from the final analysis. Thus, 150 participants (75 in each group) were included in the final analysis, as shown in the CONSORT flow diagram (Figure 1).

The mean maternal age was 27.6±2.6 years in the paracetamol group and 26.6±3.2 years in the tramadol group, with no statistically significant difference (p=0.0521). Similarly, the mean gestational age was comparable between the two groups (38.55±1.07 versus 38.50±1.14 weeks; p=0.7862). Thus, there was no statistically significant difference in maternal age or gestational age between the groups at baseline, suggesting reasonable comparability with respect to these characteristics as shown in Table 1.

The distribution across age groups was generally comparable, although age-group distribution differed significantly between the two groups, with a higher

proportion of women aged 21-25 years in the tramadol group (41.3% versus 22.7%; p=0.0384). The gravida distribution also differed significantly (p=0.0002), with more primigravida women (G1) in the tramadol group, while G3 and G4 participants were present only in the paracetamol group. The gestational-age distribution was comparable between the groups, with most participants being ≥37 weeks in both groups (89.3% versus 94.7%; p=0.2286). as shown in Table 2. These differences may reflect variation in the obstetric profile of the recruited women and the relatively small number of higher-gravida participants. These baseline obstetric differences should be considered when interpreting subsequent treatment outcomes.

Before drug administration, mean VAS scores were comparable between the paracetamol and tramadol groups (5.30±0.65 versus 5.42±0.55; p=0.2242). Following treatment, mean VAS scores were significantly lower in the paracetamol group at 1, 2, and 3 hours (4.31±0.50 versus 6.35±0.65; 4.15±0.43 versus 6.53±0.62; and 4.99±0.71 versus 6.59±0.64, respectively; all p<0.0001). Similarly, a greater proportion of women in the paracetamol group had VAS ≤4, whereas severe pain (VAS ≥7) was more frequent in the tramadol group at all post-treatment time points (p<0.001). Overall, both continuous and categorical analyses demonstrated significantly better pain relief with paracetamol than tramadol throughout the 3-hour follow-up as shown in Tables 3 and 4.

First-stage labor duration was 5.41±0.63 hours in the paracetamol group and 6.53±1.90 hours in the tramadol group (mean difference -1.11 hours, 95% CI -1.57 to -0.66; p<0.0001). Second-stage duration was 24.80±4.60 versus 29.83±10.66 minutes (mean difference -5.03 minutes, 95% CI -7.68 to -2.38; p=0.0003). The drug-to-delivery interval was 3.44±0.53 versus 3.85±0.77 hours (mean difference -0.41 hours, 95% CI -0.62 to -0.20; p=0.0002). Overall, the table demonstrates statistically significant differences in all three labor-related parameters, with shorter durations observed in the paracetamol group as shown in Table 5.

In this study maternal nausea/vomiting (12.0% versus 1.3%; p=0.0175) and drowsiness (9.3% versus 0%; p=0.0135) were significantly more frequent with tramadol, while pruritus did not differ significantly (p=0.2450); no shivering or respiratory depression occurred. Neonatal birth weight and 1-minute Apgar scores were comparable between groups, whereas a significantly higher proportion of neonates in the paracetamol group had a 5-minute Apgar score ≥9 compared with the tramadol group (97.3% versus 78.7%; p=0.0004). NICU admission was also comparable (2.7% versus 6.7%; p=0.245). Overall, paracetamol was associated with fewer maternal adverse effects and more favorable 5-minute Apgar scores, with otherwise comparable neonatal outcomes as shown in Tables 6 and 7.

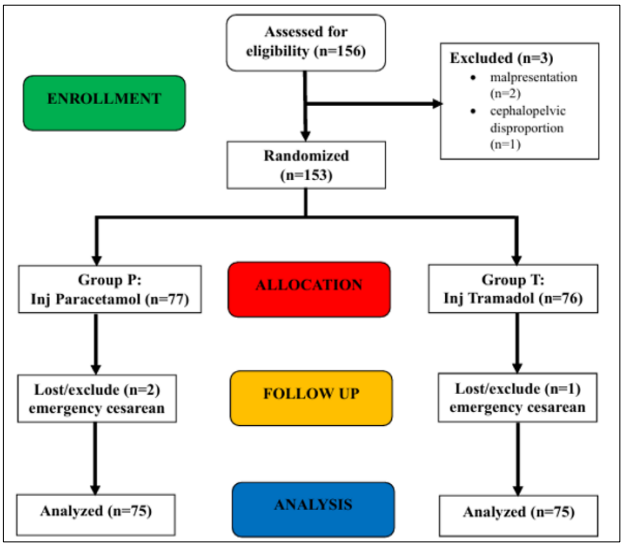


Figure 1: CONSORT diagram illustrating participant recruitment, allocation, follow-up, and analysis.

Table 1: Comparison of baseline maternal characteristics between the paracetamol and tramadol groups.

Variables	Paracetamol group (n=75)	Tramadol group (n=75)	P value*
Age (years)	27.6±2.6	26.6±3.2	0.0521
Gestational age (weeks)	38.55±1.07	38.50±1.14	0.7862

Data expressed as mean±SD; *independent (unpaired) t-test

Table 2: Comparison of baseline obstetric and demographic characteristics between the paracetamol and tramadol groups.

Variables	Category	Paracetamol group (n=75), N (%)	Tramadol group (n=75), N (%)	P value
Age group distribution (years)	21–25	17 (22.7)	31 (41.3)	0.0384*
	26–30	44 (58.7)	36 (48.0)	
	31–35	14 (18.6)	8 (10.7)	
Gravida	G1	33 (44.0)	47 (62.7)	0.0002**
	G2	24 (32.0)	28 (37.3)	
	G3	9 (12.0)	0 (0.0)	
	≥G4	9 (12.0)	0 (0.0)	

Continued.

Variables	Category	Paracetamol group (n=75), N (%)	Tramadol group (n=75), N (%)	P value
Gestational age (weeks)	<37	8 (10.7)	4 (5.3)	0.2286*
	≥37	67 (89.3)	71 (94.7)	

Data expressed as frequency (percentage); *Chi-square test; **Fisher's exact test

Table 3: Comparison of mean VAS pain scores at different time points between the paracetamol and tramadol groups.

Time of assessment	Paracetamol group (n=75)	Tramadol group (n=75)	P value*
Before drug administration	5.30±0.65	5.42±0.55	0.2242
1 hour	4.31±0.50	6.35±0.65	<0.0001
2 hours	4.15±0.43	6.53±0.62	<0.0001
3 hours	4.99±0.71	6.59±0.64	<0.0001

Data expressed as mean±S.D.; *independent (unpaired) t-test

Table 4: Comparison of VAS pain categories at different time points between the paracetamol and tramadol groups.

Time of assessment	VAS category	Paracetamol group (n=75), N (%)	Tramadol group (n=75), N (%)	P value
Before drug	≤4	8 (10.7)	5 (6.7)	0.384*
	5–6	64 (85.3)	66 (88.0)	0.631*
	≥7	3 (4.0)	4 (5.3)	1.000**
1 hour	≤4	51 (68.0)	2 (2.7)	<0.001**
	5-6	22 (29.3)	40 (53.3)	0.003*
	≥7	2 (2.7)	33 (44.0)	<0.001**
2 hours	≤4	61 (81.3)	1 (1.3)	<0.001**
	5-6	13 (17.4)	39 (52.0)	<0.001*
	≥7	1 (1.3)	35 (46.7)	<0.001**
3 hours	≤4	19 (25.3)	0 (0.0)	<0.001**
	5-6	56 (74.7)	35 (46.7)	<0.001*
	≥7	0 (0.0)	40 (53.3)	<0.001**

Data expressed as frequency (percentage); *Chi-square test; ** Fisher's exact test

Table 5: Comparison of duration of labor and drug-to-delivery interval between the paracetamol and tramadol groups.

Labor duration	Paracetamol group (n=75) mean±SD	Tramadol group (n=75) mean±SD	Mean difference	95% CI	P value*
First stage (hours)	5.41±0.63	6.53±1.90	-1.11	-1.57 to -0.66	<0.0001
Second stage (minutes)	24.80±4.60	29.83±10.66	-5.03	-7.68 to -2.38	0.0003
Drug-to-delivery interval (hours)	3.44±0.53	3.85±0.77	-0.41	-0.62 to -0.20	0.0002

*Independent (unpaired) t-test

Table 6: Comparison of maternal adverse effects between the paracetamol and tramadol groups.

Adverse effect	Paracetamol group (n=75), N (%)	Tramadol group (n=75), N (%)	Risk difference, percentage points (95% CI)	P value*
Nausea/vomiting	1 (1.3)	9 (12.0)	-10.7 (-21.0 to 0.7)	0.0175
Drowsiness	0 (0.0)	7 (9.3)	-9.3 (-18.0 to 0.3)	0.0135
Pruritus	0 (0.0)	3 (4.0)	-4.0 (-11.1 to 3.5)	0.2450
Shivering	0 (0.0)	0 (0.0)	0.0 (-4.9 to 4.9)	1.000
Respiratory depression	0 (0.0)	0 (0.0)	0.0 (-4.9 to 4.9)	1.000

Data expressed as frequency (percentage); *Fisher's exact test

Table 7: Comparison of neonatal outcomes between the paracetamol and tramadol groups.

Neonatal outcome	Category	Paracetamol group (n=75), N (%)	Tramadol group (n=75), N (%)	P value
Birth weight (kg)	<2.5	11 (14.7)	8 (10.7)	0.461*
	≥2.5	64 (85.3)	67 (89.3)	
Apgar at 1 minute	<7	0 (0.0)	0 (0.0)	1.000**
	≥7	75 (100.0)	75 (100.0)	
Apgar at 5 minutes	<9	2 (2.7)	16 (21.3)	0.0004*
	≥9	73 (97.3)	59 (78.7)	
NICU admission	No	73 (97.3)	70 (93.3)	0.442**
	Yes	2 (2.7)	5 (6.7)	

Data expressed as frequency (percentage); *Chi-square test; ** Fisher's exact test

DISCUSSION

Labor pain is influenced by physiological, psychological, and social factors and may induce maternal stress responses. Effective analgesia should provide adequate pain relief without compromising maternal or fetal safety.[1,2] This randomized controlled trial compared intravenous paracetamol 1 g and intramuscular tramadol 100 mg for analgesia during active labor. A total of 153 women were randomized, of whom 150 were included in the final analysis as 3 participants underwent emergency cesarean delivery and were excluded. Pain intensity was assessed using VAS before treatment and at 1, 2, and 3 hours, along with duration of labor, drug-to-delivery interval, maternal adverse effects, and neonatal outcomes.

Efficacy

The principal finding of the present study was the significantly greater reduction in pain intensity with intravenous paracetamol compared with intramuscular tramadol. Before administration of the study drug, mean VAS scores were comparable between the paracetamol and tramadol groups. Following treatment, the mean VAS score was significantly lower in the paracetamol group at all assessed time points. These findings are consistent with previous evidence supporting the effectiveness of intravenous paracetamol as a systemic analgesic during labor. Lallar et al reported greater reduction in pain intensity with intravenous paracetamol compared with intramuscular tramadol, together with a shorter duration of labor and a higher frequency of nausea and vomiting in women receiving tramadol.[12] Similarly, Mohan et al compared intravenous paracetamol with intramuscular tramadol and reported greater pain relief with paracetamol, together with shorter labor duration and fewer maternal adverse effects.[13] Das et al also reported significantly lower pain scores and shorter labor duration with intravenous paracetamol compared with intramuscular tramadol.[14] The findings are further supported by Marwah et al who demonstrated better pain relief with intravenous paracetamol compared with tramadol in their randomized controlled trial.[15] Monisha and Poomalar similarly reported greater and more sustained pain reduction with intravenous paracetamol, along with fewer maternal adverse effects.[16] Jindal et al reported significantly lower VAS scores with intravenous paracetamol at 1 hour compared with intravenous tramadol, whereas the difference at 3 hours was not statistically significant.[1] Thus, the consistency between their findings and those of the present study strengthens the evidence that intravenous paracetamol can provide clinically meaningful systemic analgesia during active labor.

Categorical VAS analysis further supported the continuous VAS findings. While baseline pain categories were comparable, significantly more women receiving paracetamol had VAS ≤4 after treatment, whereas severe pain (VAS ≥7) was more frequent with tramadol at 1, 2, and 3 hours. This shift toward lower pain categories indicates a clinically meaningful improvement with paracetamol, beyond a difference in mean VAS scores. This finding is particularly relevant in clinical practice because an effective labor analgesic should ideally reduce pain to a level that is acceptable to the woman rather than merely produce a statistically significant change in a numerical pain score. The superior analgesic effect of paracetamol may be related to its established central analgesic mechanisms and its non-opioid pharmacological profile. Przybyła et al described the evolving understanding of the analgesic mechanisms of paracetamol, while Allegaert and van den Anker discussed its established use and safety in the perinatal period.[5,6] The present findings provide clinical support for the potential use of intravenous paracetamol as a systemic analgesic during labor.

Labor duration

In the present study, the duration of both the first and second stages of labor was significantly shorter in the paracetamol group. The drug-to-delivery interval was also significantly shorter with paracetamol (3.44±0.53 versus 3.85±0.77 hours; p=0.0002). These findings are consistent with those reported by Makkar et al who observed a shorter first stage of labor with paracetamol.[11] Lallar et al also reported a shorter duration of labor with intravenous paracetamol, while Mohan et al reported similar reductions in labor duration with paracetamol compared with tramadol.[12,13] One possible explanation is that better analgesia may reduce maternal stress and sympathetic

activation, potentially facilitating labor.[1,2] However, baseline differences in gravida and onset of labor may have influenced these outcomes. Therefore, the shorter labor duration should be interpreted as an association rather than a direct effect of paracetamol.

Safety

The present study found significantly fewer maternal adverse effects with intravenous paracetamol. Nausea/vomiting and drowsiness were less frequent with paracetamol than tramadol. Pruritus was also less frequent with paracetamol, although the difference was not statistically significantly (0.2450). No shivering or respiratory depression occurred in either group. These findings are consistent with the pharmacological profile of the two drugs. Tramadol is a centrally acting opioid analgesic with weak μ-opioid receptor agonist activity as well as serotonergic and noradrenergic effects.[9] Bloor et al specifically discussed the use of tramadol during pregnancy and lactation and highlighted considerations related to maternal and neonatal exposure.[9] The findings of the present study are also in agreement with Lallar et al who reported more frequent nausea and vomiting with intramuscular tramadol, and with Mohan et al and Monisha and Poomalar who reported fewer maternal adverse effects with intravenous paracetamol.[12,13,16] From a clinical perspective, the lower incidence of nausea, vomiting, and drowsiness may represent an important advantage of paracetamol, particularly because women in labor may already experience nausea and fatigue. Avoiding additional sedation may also facilitate maternal interaction and participation during labor.

Neonatal outcomes were generally comparable between groups. Birth weight and 1-minute Apgar scores did not differ significantly, while a significantly higher proportion of neonates in the paracetamol group had a 5-minute Apgar score ≥9. NICU admission was also comparable (2.7% versus 6.7%; p=0.245). These findings suggest no obvious adverse effect of either analgesic on immediate neonatal outcomes. The higher 5-minute Apgar scores with paracetamol may reflect the absence of opioid-related neonatal effects, although this should be interpreted cautiously because Apgar scores are influenced by multiple factors and the study was not powered to assess neonatal morbidity. The findings are consistent with the recognized importance of minimizing fetal opioid exposure during labor.[6,10] Overall, no significant difference in NICU requirement was demonstrated.

Strengths and limitations

The major strength of the present study is its prospective randomized controlled design, with equal allocation of 150 participants in the final analysis. The study evaluated both subjective analgesic efficacy and clinically relevant maternal and neonatal safety outcomes. Repeated assessment of VAS scores at predefined time points allowed evaluation of analgesic effects over the first 3 hours following administration. However, the study had several limitations. It was single-center and open-label, limiting generalizability and introducing potential performance or assessment bias. Baseline differences in gravida and onset of labor may have influenced labor-duration outcomes. Three participants were excluded from the final analysis after randomization because of emergency cesarean delivery, so exclusion after randomization may introduce attrition bias. The sample size of 150 may have been insufficient to detect rare maternal or neonatal adverse events. Additionally, neonatal assessment was limited to birth weight, Apgar scores, and NICU admission, without evaluation of longer-term outcomes.

CONCLUSION

In this randomized controlled trial, intravenous paracetamol was associated with lower post-treatment VAS pain scores and fewer maternal adverse effects than intramuscular tramadol during active labor. Labor duration and the drug-to-delivery interval were also shorter in the paracetamol group, although these findings should be interpreted cautiously because of baseline obstetric differences. Birth weight, 1-minute Apgar scores, and NICU admission were comparable, while 5-minute Apgar score ≥9 was more frequent with paracetamol. Intravenous paracetamol may be considered a systemic analgesic option during active labor when neuraxial analgesia is unavailable, contraindicated, or not preferred. Larger multicenter studies with longer neonatal follow-up are warranted.

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