

A Case-Control Study on the Efficacy of Intravenous Paracetamol for Labor Analgesia: Impact on Pain Reduction and Duration of Labor

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Abstract: **Background:** Labor pain is a significant challenge in obstetric care, necessitating safe and effective analgesic options. Intravenous paracetamol has emerged as a promising non-opioid analgesic for intrapartum pain relief. **Objective:** To evaluate the efficacy of intravenous paracetamol in reducing labor pain and shortening the duration of labor in a case-control study. **Methods:** This was a case-control study including 128 participants (64 in the paracetamol group and 64 in the placebo group). Pain intensity was assessed using the McGill's Pain Intensity Scale before, 1 hour, and 3 hours after drug administration. Labor duration, mode of delivery, and neonatal outcomes were also analyzed. Statistical analysis was performed using independent t-tests, with a significance level of $p < 0.05$. **Results:** The paracetamol group showed a significant reduction in pain intensity at both 1 hour ($p < 0.001$) and 3 hours ($p < 0.001$) compared to the placebo group. Additionally, the total duration of labor was significantly shorter in the paracetamol group ($p < 0.001$). No significant differences were observed in neonatal Apgar scores or birth weight between the groups. **Conclusion:** Intravenous paracetamol is an effective and safe labor analgesic, reducing pain intensity and shortening labor duration without adverse maternal or neonatal effects. This study supports its use as a feasible option for intrapartum pain management in resource-limited settings.

Keywords: Intravenous Paracetamol, Labor Pain Management, Analgesia in Obstetrics, Labor Duration, Maternal and Neonatal Outcomes

INTRODUCTION

Labor pain is a complex and multifactorial phenomenon, arising from uterine contractions, cervical dilation, and perineal stretching. Effective pain management during labor is crucial not only for maternal comfort but also for optimizing obstetric outcomes and reducing stress-induced complications (1). Uncontrolled labor pain can lead to increased maternal catecholamine release, which may result in reduced uteroplacental perfusion and fetal distress (2).

Various pharmacological and non-pharmacological pain relief methods have been employed in obstetric practice, ranging from epidural analgesia to opioid administration and complementary therapies like acupuncture and hydrotherapy (3). Epidural analgesia is widely recognized as the gold standard for labor analgesia; however, it requires specialized equipment and personnel, making it inaccessible in many low-resource settings (4). Alternative systemic analgesics such as pethidine and tramadol have been used but are associated with adverse effects like maternal sedation, nausea, and neonatal respiratory depression (5).

Given these challenges, intravenous paracetamol has gained interest as a potential intrapartum analgesic due to its favorable safety profile, ease of administration, and rapid onset of action (6). Previous studies have demonstrated that intravenous paracetamol effectively reduces postoperative and musculoskeletal pain, supporting its potential application in labor analgesia (7).

However, there is limited research evaluating its role in managing labor pain and its effects on labor progression and neonatal outcomes (8).

This study aims to bridge this knowledge gap by systematically assessing the efficacy of intravenous paracetamol in reducing labor pain intensity and its impact on the duration of labor.

Objectives:

The primary objective of this study is to evaluate the effectiveness of intravenous paracetamol in reducing labor pain compared to a placebo. Specifically, the study aims to compare pain intensity between the paracetamol and placebo groups at baseline, 1 hour, and 3 hours after administration, providing insight into the short-term analgesic effects of the drug.

Additionally, the study assesses the impact of intravenous paracetamol on the duration of labor stages, analyzing whether its use contributes to a reduction in total labor time. Furthermore, neonatal outcomes, including Apgar scores at 1 and 5 minutes and birth weight, are examined to determine any potential effects of paracetamol administration on fetal well-being.

This study hypothesizes that intravenous paracetamol significantly reduces labor pain intensity and shortens labor duration without adversely affecting neonatal outcomes.

METHODOLOGY:

This case-control study compared the efficacy of intravenous paracetamol to placebo in reducing labor pain and affecting labor duration. The study was conducted in the Obstetrics and Gynecology department of a Saveetha medical college and research institute over a 6-month period. Recruitment of participants took place between June 2024 and December 2024, and data collection included patient demographics, pain scores, duration of labor, and neonatal outcomes.

Primigravida women in active labor (cervical dilatation ≥ 3 cm), carrying a single, live, intrauterine fetus in cephalic presentation with a gestational age of ≥ 37 weeks, and without contraindications to paracetamol were eligible for inclusion.

Women with multiple gestations, a history of allergy to paracetamol, medical disorders such as hepatic or renal disease, fetal distress at recruitment, or prior cesarean section or uterine surgery were excluded.

Participants were randomly assigned to either the Paracetamol Group ($n=64$) or the Placebo Group ($n=64$) using a computerized random number generator to ensure unbiased allocation.

The primary outcome was the reduction in pain intensity, assessed using the McGill's Pain Intensity Scale at baseline, 1 hour, and 3 hours post-administration. Secondary outcomes included total labor duration (across all three stages), mode of delivery (vaginal, instrumental, or cesarean section), neonatal outcomes (Apgar scores at 1 and 5 minutes, birth weight), and maternal side effects (nausea, vomiting, hypotension, fever).

Pain intensity was recorded using the McGill's Pain Intensity Scale, labor duration from active labor onset to delivery, and neonatal outcomes using standardized neonatal assessment protocols. All data were collected by trained obstetricians and nurses to ensure consistency. To minimize observer bias, both participants and outcome assessors were blinded to treatment allocation. Standardized assessment tools ensured uniform data collection, and randomization helped maintain balance across groups.

The study size was calculated based on an 80% power and a 0.05 significance level to detect a clinically meaningful reduction in pain intensity. A total of 128 participants (64 per group) was determined to be adequate.

Continuous variables, including pain scores, labor duration, and Apgar scores, were summarized using means and standard deviations, while categorical variables such as mode of delivery and maternal side effects were analyzed using frequencies and percentages. Variables were grouped into clinically relevant

categories. Independent t-tests were used to compare mean pain scores and labor duration between groups, while chi-square tests were used for categorical variables such as mode of delivery. Subgroup analyses were conducted to assess whether paracetamol had differential effects based on mode of delivery (vaginal vs. caesarean births). Missing data were minimized through meticulous data collection, and in cases of missing values, multiple imputation methods were used to prevent bias. A 1:1 stratified randomization method ensured balance in baseline characteristics. Sensitivity analyses were conducted by excluding participants with protocol deviations to confirm the robustness of findings. This study followed rigorous methodological standards to evaluate the effectiveness and safety of intravenous paracetamol in labor analgesia, ensuring transparency and reproducibility of results.

RESULTS

A total of 180 women were assessed for eligibility, out of which 52 did not meet the inclusion criteria. Consequently, 128 participants were enrolled in the study and randomly assigned to either the Paracetamol Group ($n=64$) or the Placebo Group ($n=64$) using a computerized random number generator to ensure unbiased allocation. During the study, six participants from each group were lost to follow-up, leaving 58 participants in each group for the final analysis. The reasons for non-participation included withdrawal of consent ($n=4$), development of exclusion criteria post-randomization ($n=6$), and loss to follow-up due to unavailability ($n=2$).

The mean age of participants in the Paracetamol group was 26.1 ± 2.9 years, while in the Placebo group, it was 25.9 ± 3.2 years ($p = 0.45$). The mean gestational age at enrollment was 38.75 ± 1.1 weeks in the Paracetamol group and 38.55 ± 1.3 weeks in the Placebo group ($p = 0.32$). The cervical dilatation at enrollment was 3.57 ± 0.28 cm in the Paracetamol group and 3.59 ± 0.27 cm in the Placebo group ($p = 0.58$). Cervical effacement was also comparable ($68.2\% \pm 4.9\%$ vs. $67.8\% \pm 5.1\%$, $p = 0.61$) (Table 1).

Before drug administration, there was no significant difference in pain scores between the two groups ($p = 0.49$). However, at 1 hour after drug administration, the Paracetamol group exhibited significantly lower pain intensity compared to the Placebo group ($p < 0.001$), and this effect was sustained at 3 hours post-administration ($p < 0.001$) (Table 2). These findings confirm the prolonged analgesic effect of intravenous paracetamol in labor pain management.

The mean duration of the first stage of labour was 218.5 ± 14.8 minutes in the Paracetamol group compared to 326.3 ± 20.7 minutes in the Placebo group ($p < 0.001$). Similarly, the second stage of labour was shorter in the Paracetamol group (34.2 ± 4.8 minutes) compared to the Placebo group (42.6 ± 2.3 minutes, $p < 0.001$) (Table 3).

The total duration of labour was significantly shorter in the Paracetamol group ($p < 0.001$), indicating a beneficial effect of intravenous paracetamol on labor progression.

Apgar scores at 1 minute were similar between the groups (Paracetamol: 8.42 ± 1.02 vs. Placebo: 8.46 ± 1.05 , $p = 0.59$), as were the Apgar scores at 5 minutes (Paracetamol: 9.90 ± 0.28 vs. Placebo: 9.88 ± 0.30 , $p = 0.72$). Birth weight was comparable in both groups (Paracetamol: 2.54 ± 0.26 kg vs. Placebo: 2.60 ± 0.31 kg, $p = 0.47$) (Table 4), indicating no adverse impact on neonatal health.

The mode of delivery did not significantly differ between groups. Spontaneous vaginal delivery occurred in 91.5% of the Paracetamol group and 90.2% of the Placebo group ($p = 0.69$). Lower segment caesarean section (LSCS) was required in 7.5% of the Paracetamol group and 8.1% of the Placebo group, while ventouse-assisted vaginal delivery was observed in 1% of the Paracetamol

group, with none recorded in the Placebo group (Table 5).

The time from drug administration to delivery was significantly shorter in the Paracetamol group (2.92 ± 0.34 hours) compared to the Placebo group (3.25 ± 0.42 hours, $p < 0.001$) (Table 6), suggesting that intravenous paracetamol facilitates faster labour progression. The Paracetamol group reported mild nausea (2%) and vomiting (2%). No significant adverse effects such as respiratory depression, fetal tachycardia, or hypotension were observed in either group.

Subgroup analyses examined whether intravenous paracetamol had differential effects based on mode of delivery. The findings were consistent across all subgroups, with no significant interaction effects observed. Sensitivity analyses were performed by excluding participants with protocol deviations, and the results remained robust, further validating the primary findings.

Maternal age, Gestational age, Mean Cervical Dilatation and Effacement

Parameter	Paracetamol Group (Mean $\pm$ SD)	Placebo Group (Mean $\pm$ SD)	p-value
Mean Age (years)	26.1 $\pm$ 2.9	25.9 $\pm$ 3.2	0.45
Mean Gestational Age (weeks)	38.75 $\pm$ 1.1	38.55 $\pm$ 1.3	0.32
Mean Cervical Dilatation (cm)	3.57 $\pm$ 0.28	3.59 $\pm$ 0.27	0.58
Mean Cervical Effacement (%)	68.2 $\pm$ 4.9	67.8 $\pm$ 5.1	0.61

Table 1

Pain intensity before, after and 3 hour drug administration

Time Point	Pain Intensity	Paracetamol Group (n, %)	Placebo Group (n, %)	p-value
Before Drug Administration	Mild	0 (0%)	0 (0%)	0.49
	Discomfort	10 (16%)	6 (9%)	
	Distressing	50 (78%)	52 (81%)	
	Horrible	4 (6%)	6 (10%)	
1 Hour After Administration	Mild	5 (8%)	0 (0%)	<0.001
	Discomfort	35 (55%)	15 (23%)	
	Distressing	22 (34%)	40 (63%)	
	Horrible	2 (3%)	9 (14%)	
3 Hours After Administration	Mild	10 (16%)	3 (5%)	<0.001
	Discomfort	48 (75%)	20 (31%)	
	Distressing	5 (8%)	30 (47%)	
	Horrible	1 (1%)	11 (17%)	

Table 2

Duration of labour

Stage of Labour	Paracetamol Group (Mean $\pm$ SD) (mins)	Placebo Group (Mean $\pm$ SD) (mins)	p-value
First Stage	218.5 $\pm$ 14.8	326.3 $\pm$ 20.7	<0.001
Second Stage	34.2 $\pm$ 4.8	42.6 $\pm$ 2.3	<0.001
Total Duration	252.7 $\pm$ 15.2	368.9 $\pm$ 18.4	<0.001

Table 3

Mean Apgar score at 1 min and 5 min and Birth weight			
Parameter	Paracetamol Group (Mean ± SD)	Placebo Group (Mean ± SD)	p-value
Apgar Score (1 min)	8.42 ± 1.02	8.46 ± 1.05	0.59
Apgar Score (5 min)	9.90 ± 0.28	9.88 ± 0.30	0.72
Birth Weight (kg)	2.54 ± 0.26	2.60 ± 0.31	0.47

Table 4

Mode of delivery		
Mode of Delivery	Paracetamol Group	Placebo Group
Vaginal (%)	91.5%	90.2%
LSCS (%)	7.5%	8.1%
Ventouse (%)	1.0%	0%

Table 5

Drug delivery interval			
Parameter	Paracetamol Group (Mean ± SD)	Placebo Group (Mean ± SD)	p-value
Drug Administration to Delivery (hours)	2.92 ± 0.34	3.25 ± 0.42	<0.001

Table 6

DISCUSSION:

This study found that intravenous paracetamol significantly reduced labor pain intensity at 1 and 3 hours post-administration and shortened the total duration of labor. Importantly, neonatal outcomes, including Apgar scores and birth weight, were not adversely affected. These findings are consistent with previous studies, such as Elbohoty et al. (2012) (7) and Abdollahi et al. (2014) (8), who demonstrated similar analgesic effects of intravenous paracetamol in labor pain management. Additionally, studies by Makkar et al. (2015) (5) and Wong (2009) (3) support these results, highlighting the non-opioid analgesic properties of intravenous paracetamol as a viable alternative to traditional opioid-based analgesia.

Our results align with findings from studies by Meenakshi Lallar et al. (9) and Hema Mohan et al., (10) which also reported a significant reduction in pain intensity at 1 and 3 hours following intravenous paracetamol administration, reinforcing its efficacy as a labor analgesic option. The effectiveness of acetaminophen infusion in reducing pain scores at all intervals compared to placebo has been emphasized in prior research (11). Some studies have even suggested that the analgesic efficacy of acetaminophen infusion is superior to opioids such as tramadol and pethidine (12,13).

The results support the hypothesis that intravenous paracetamol is an effective labor analgesic with minimal maternal or neonatal adverse effects. Compared to opioids, it offers a non-opioid alternative with fewer side effects and a better safety profile. The analgesic

mechanism of acetaminophen is likely due to its central inhibition of cyclooxygenase and serotonergic pathway modulation. The findings from randomized controlled trials comparing the analgesic efficacy of acetaminophen infusion with opioids such as pethidine and nalbuphine further support these conclusions (14,15). However, contradictory reports in the literature suggest that acetaminophen infusion may not be as efficacious as opioids beyond the initial two to three hours of administration (16–18). This discrepancy underscores the need for additional comparative studies evaluating the long-term efficacy of acetaminophen infusion in labor analgesia.

Despite the promising findings, certain limitations must be acknowledged. The study was conducted on a relatively small cohort, which may limit the generalizability of the results. Additionally, potential biases, such as subjective variations in pain perception and reliance on the McGills pain intensity scale, could have influenced the outcomes. The duration of analgesic efficacy has also been debated in previous literature, with some studies reporting that the effect of acetaminophen infusion lasts only two to three hours post-administration and is less efficacious than opioids such as pethidine, meperidine, and nalbuphine (16–18). These variations highlight the need for further studies with larger sample sizes and diverse populations to validate the findings.

The study results are relevant to clinical settings where opioid-based analgesia may not be feasible or desirable due to associated side effects and monitoring requirements. Intravenous paracetamol provides an accessible, cost-effective, and easy-to-administer option, especially in resource-limited settings. However,

variations in study populations, labor protocols, and healthcare infrastructure may affect the external validity of these findings. Larger multicentric studies are warranted to establish the widespread applicability of intravenous paracetamol as a standard labor analgesic.

CONCLUSION

This study demonstrates that intravenous paracetamol is an effective and safe analgesic for labor pain management. Pain intensity was significantly reduced at both 1 hour and 3 hours after administration ($p < 0.001$), confirming its sustained analgesic effect. Additionally, the total duration of labor was markedly shorter in the Paracetamol group ($p < 0.001$), indicating its potential role in facilitating labor progression. Importantly, there were no significant differences in neonatal outcomes, including Apgar scores and birth weight, between the groups. Furthermore, paracetamol did not adversely affect maternal health, and the mode of delivery remained unaffected. These findings support the use of intravenous paracetamol as a safe and effective option for labor analgesia, particularly in settings where epidural analgesia may not be readily available.

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