Original Article

DOI: 10.7860/JCDR/2026/82423.23427

Efficacy of Intravenous Paracetamol Infusion versus Intravenous Pentazocine for Labour Analgesia: A Prospective Observational Study

Obstetrics and Gynaecology Section

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ABSTRACT

Introduction: Labour pain is recognised as one of the most intense pain experiences. While neuraxial analgesia remains the gold standard, its limited accessibility in resource-constrained settings necessitates the use of systemic agents.

Aim: The present study compares the analgesic efficacy, maternal-fetal outcomes, and side-effect profiles of Intravenous (i.v.) paracetamol versus i.v. pentazocine.

Materials and Methods: The present prospective observational study was conducted from December 2017 to May 2019 at Kempegowda Institute of Medical Sciences, Bangalore, India. A total of 60 primigravida parturients were divided into two groups: Group A (n=30) received i.v. paracetamol (1g), and Group B (n=30) received i.v. pentazocine (30 mg) during the active phase of labour. Pain relief was assessed using the McGill Pain Intensity Scale at 0, 1, 2, and 4 hours post-administration. Maternal cardiorespiratory parameters, labour duration, mode of delivery, and neonatal outcomes were recorded. Statistical Package for the Social Sciences (SPSS) version 20 was used for statistical analysis.

Results: The mean age was 25.3±3.2 years in Group A and 24.9±3.6 years in Group B. Group A, consisting of i.v. paracetamol, demonstrated significantly greater analgesic efficacy (mean McGill score at 2 h: 1.80 vs 2.62; p<0.001) with fewer maternal side-effects (0% vs 16.6%). Neonatal outcomes favoured paracetamol, with one neonate in the pentazocine group having APGAR (Appearance, Pulse, Grimace, Activity, and Respiration) score <7 at one minute (p=0.3) and no cases of APGAR <7 at five minutes in either group. No significant differences were observed in labour duration or delivery mode.

Conclusion: Both intravenous paracetamol and pentazocine provided effective analgesia for labour. Paracetamol seemed to be more effective achieving a greater reduction in pain scores compared to pentazocine, and has less maternal side-effects.

Keywords: Acetaminophen, Analgesics, Labour pain, Neonatal outcome, Obstetrical, Pregnancy

INTRODUCTION

Labour pain is considered one of the most intense forms of pain experienced by women and is often associated with significant physiological and psychological stress. Effective pain relief during labour is critical not only for maternal comfort but also for ensuring optimal obstetric outcomes [1,2]. Analgesia during labour can be provided through various pharmacological and non-pharmacological methods, with systemic opioids and i.v. non-opioid analgesics being among the most commonly used modalities in settings where neuraxial analgesia is either contraindicated or unavailable [3].

Pentazocine, a synthetic opioid with mixed agonist-antagonist properties, has been widely used for labour analgesia due to its efficacy, lower risk of respiratory depression, and minimal neonatal side-effects [4]. However, it is not devoid of adverse effects such as nausea, vomiting, and sedation or dizziness [5]. In recent years, there has been growing interest in the use of non-opioid agents such as i.v. paracetamol for labour analgesia [1,6,7]. Intravenous paracetamol acts centrally by inhibiting prostaglandin synthesis and modulating serotonergic pathways, offeracetaing effective analgesia with a favourable safety profile and minimal sedative properties [6].

Study have examined the role of intravenous paracetamol in managing postoperative and procedural pain, and its use is gaining traction in obstetric analgesia due to the absence of opioid-related side-effects [8]. Yet, there remains a paucity of data directly comparing intravenous paracetamol with traditional opioids like pentazocine for labour analgesia in the Indian population.

Thus, the present prospective, observational study aimed to evaluate and compare the efficacy and safety profiles of intravenous paracetamol versus intravenous pentazocine for labour analgesia in term parturients. The primary outcomes include pain relief assessed by the McGill pain scale, while secondary outcomes include maternal side-effects, neonatal outcomes, and the duration of labour.

MATERIALS AND METHODS

The present prospective, observational study was conducted at Kempegowda Institute of Medical Sciences, a tertiary care, teaching Medical College Hospital in urban areas of Bangalore, India, from December 2017 to May 2019. The study was approved by the Institutional Ethics Committee (KIMS/IEC/D-65/2017).

Inclusion and Exclusion criteria: The inclusion criteria were term primigravida, singleton pregnancies (≥37 weeks), vertex presentation, spontaneous or induced labour, and cervical dilation of 3-4 cm. Parturients with high-risk pregnancies {e.g., eclampsia, diabetes, Intrauterine Growth Restriction (IUGR)}, scarred uterus, clinical cephalopelvic disproportion, and oligohydramnios (Amniotic Fluid Index (AFI) <5 cm) were excluded.

Sample size: The sample size was determined using the formula for comparing mean changes between two independent groups:

$$n_{\text{per group}} = \frac{2\,(Z_{1-\alpha/2}+Z_{1-\beta})^2\,\sigma^2}{\Delta^2}.$$

A two-sided significance level of 0.05 (95% confidence) and a statistical power of 80% were assumed, corresponding to $Z_{1-\alpha/2}$=1.96 and $Z_{1-\beta}$=0.842, respectively. The pooled standard deviation of the change in McGill Pain scores from a reference study was calculated as 0.697 [9]. The expected difference between the mean changes in McGill Pain scores was 0.61. Substituting these

parameters into the sample size equation yielded an estimated requirement of 21 participants per group (42 in total), which was deemed sufficient to achieve the desired confidence and power. However, 30 participants were ultimately enrolled in each group, enhancing the precision and robustness of the study findings. Participants were enrolled consecutively until the required sample size was achieved.

Demographic details and a detailed antenatal history of the present pregnancy, medical history and obstetric history were recorded. Clinical examination including obstetrical examination and per vagina examination were performed. Labour details prior to recruitment in the study were also documented.

Based on the analgesic administered as part of routine clinical practice, participants were categorised into two groups: Group A (i.v. paracetamol) and Group B (i.v. pentazocine). The choice of analgesic was determined by the attending clinical team, and the investigator documenting outcomes was not involved in the decision-making process.

Intervention and Assessments

Participants received either i.v. paracetamol infusion (1000 mg) or i.v. pentazocine (30 mg) diluted with 9 mL of normal saline and administered over 20 minutes for labour analgesia, as per standard clinical protocol. Prior to drug administration, a baseline McGill Pain Score was recorded [10]. Pain intensity was subsequently evaluated at 1, 2, and 4 hours using the McGill Pain Intensity Scale. Repeat dosing after four hours was permitted when clinically indicated, reflecting real-world, individualised labour pain management practices.

Labour progress was monitored using a partograph, and additional clinical parameters including mode of delivery, duration of labour, neonatal outcomes (APGAR score), and drug-related side-effects were systematically documented.

STATISTICAL ANALYSIS

Descriptive data were analysed using SPSS version 20.0. Descriptive statistics including proportion, mean, standard deviation, and interferential statistics like Chi-square test were used to calculate statistical significance. Categorical data were expressed as frequencies and percentages and analysed by Chi-square. Continuous variables that were not normally distributed were analysed using Mann-Whitney U-test. A p-value of <0.05 was determined to be statistically significant.

RESULTS

The mean age of participants was 25.3±3.2 years in the paracetamol group and 24.9±3.6 years in the pentazocine group (p=0.68) [Table/Fig-1].

Variables	Paracetamol (Group A, n=30)	Pentazocine (Group B, n=30)	p-value
Mean age (years)	25.3±3.2	24.9±3.6	0.68
Primigravida (%)	30 (100%)	30 (100%)	-
Mean GA (weeks)	38.8±1.1	38.6±1.3	0.08

[Table/Fig-1]: Demographic profile of study participants.
Abbv: GA - Gestational Age; Note: Mann–Whitney test was employed

Pain intensity, as assessed using the McGill Pain Questionnaire, was significantly lower in the paracetamol group at all measured time points post-administration compared to the pentazocine group [Table/Fig-2]. The before-and-after McGill Pain Score data for both paracetamol and pentazocine were compared at baseline and at four hours using the Mann-Whitney test, and in each group the reduction in pain scores was statistically significant, with p-values of less than 0.001. There was no statistically significant difference in the mean duration of labour between the two groups [Table/Fig-3].

No neonates in either group had an APGAR score <7 at five minutes, except one neonate in the pentazocine group who had an APGAR score <7 at one minute, though this was not statistically significant (p=0.3) [Table/Fig-4].

Time post-dose	Paracetamol (Group A)	Pentazocine (Group B)	p-value
Baseline	4.03±0.66	4.20±0.56	0.30
1 hour	2.23±0.63	3.47±0.63	<0.001
2 hours	1.80±0.40	2.62±1.17	<0.001
4 hours	1.30±0.47	1.93±1.16	<0.001

[Table/Fig-2]: Comparison of McGill pain scores over time between paracetamol and pentazocine groups.
Note: Mann-Whitney test was employed

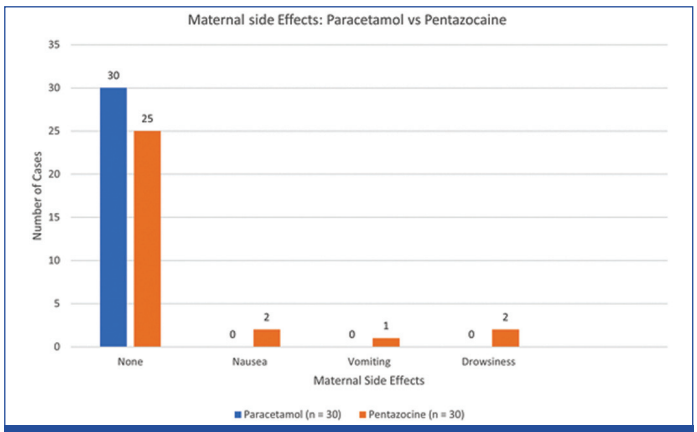
Group	Mean duration (min)±SD	p-value
Paracetamol (Group A)	293.13±81.73	0.72
Pentazocine (Group B)	280.10±117.51	

[Table/Fig-3]: Comparison of mean duration of labour between paracetamol and pentazocine groups.
Note: Mann–Whitney test was employed

Outcome	Paracetamol (Group A)	Pentazocine (Group B)	p-value
APGAR <7 at 1 min	0	1	0.3
APGAR <7 at 5 min	0	0	-
TTNB/Depression	0	3	0.03
Hyperbilirubinemia	5	1	NS

[Table/Fig-4]: Comparison of neonatal outcomes between intravenous paracetamol and pentazocine groups.
Abbv: TTNB: Transient tachypnea of the newborn; NS: Not significant; Note: Chi-square test was employed

As illustrated in [Table/Fig-5], maternal side-effects were more frequently reported in the pentazocine group, with 6.7% experiencing nausea, 6.7% drowsiness, and 3.3% vomiting. In contrast, side-effects in the paracetamol group were minimal and not clinically significant.



[Table/Fig-5]: Comparison of maternal side-effects between intravenous paracetamol and Pentazocine.

DISCUSSION

The present prospective observational study demonstrates that both i.v. paracetamol and pentazocine are effective in labour analgesia. However, paracetamol exhibited noticeably greater pain relief at all measured time points with fewer maternal side-effects. The present findings complement and expand on existing literature. In a direct comparative study, Muhammad Z et al., (2017) evaluated the analgesic efficacy of IM pentazocine versus i.v. paracetamol in 100 pregnant women undergoing labour [11]. Similar to the present study's safety profile, their results indicated that while the two medications provided comparable levels of pain relief, the paracetamol group experienced noticeably fewer adverse effects, including nausea, drowsiness, and vomiting.

Similarly, a randomised controlled trial comparing pentazocine with a tramadol–paracetamol combination was conducted by Opadiran RO et al., (2022) [12]. Although pentazocine showed stronger early analgesia, the combination group demonstrated better tolerability, thereby highlighting the consistent trend of fewer side-effects when paracetamol is involved. Although our study directly compares intravenous paracetamol with pentazocine, we have included reference studies involving other opioids such as pethidine and tramadol. These agents share similar mechanisms of action and are commonly used in clinical practice for labour analgesia, making them relevant comparators. Their inclusion provides a broader context and reinforces the consistent analgesic efficacy and favourable safety profile of paracetamol when assessed against various opioids. This approach enhances the generalisability of our findings and further supports the use of paracetamol as a viable alternative in obstetric pain management.

A recent randomised trial by Anter ME et al., (n=96) further supports these trends, showing that i.v. paracetamol produced steadily improving analgesia and demonstrated an excellent maternal safety profile, with only 2.1% experiencing dizziness and 4.2% reporting nausea or vomiting. Neonatal outcomes were similarly reassuring, with 95.8% achieving good APGAR scores at 1 and 5 minutes and only 4.2% requiring resuscitation, reflecting overall favourable fetal well-being [13]. Additionally, Goel S conducted a randomised study in 20 parturients comparing acetaminophen with pentazocine and found significantly lower pain scores at one hour in the acetaminophen group (VAS 6.9 vs. 5.5), with continued favourable reduction at two hours (0.39 vs. 0.89). The authors concluded that acetaminophen is a suitable and effective parenteral alternative to pentazocine for labour analgesia [14].

Supporting these observations, a large randomised trial by Opadiran RO et al., (n=214) reported that maternal side-effects were significantly less frequent with paracetamol-containing regimens, with nausea occurring in 14.7% compared to 38.1% and drowsiness in 8.7% compared to 19.1% in the pentazocine group, while neonatal outcomes including APGAR scores and Special Care Baby Unit (SCBU) admissions, remained comparable between both groups [12]. This collective evidence enhances the generalisability of our findings and supports the use of paracetamol as a viable and safer alternative in obstetric pain management.

Limitation(s)

The present study has certain limitations. First, the prospective observational design limits the ability to establish causality, as participants were not randomised and the choice of analgesic was determined by the attending clinician, introducing potential selection bias. Second, the sample size was relatively small and included only primigravida women from a single tertiary centre, which may limit the generalisability of the findings to broader obstetric populations. Third, pain perception is inherently subjective, and although a validated tool (McGill Pain Intensity Scale) was used, individual variability may still influence reported scores. Additionally, long-term neonatal outcomes and maternal satisfaction were not assessed, preventing a more comprehensive evaluation of the overall impact of the analgesics. Future multicenter randomised controlled trials with larger sample sizes are recommended to validate and extend these findings.

CONCLUSION(S)

The i.v. paracetamol provided effective labour analgesia with fewer maternal side-effects and comparable neonatal outcomes, making it a safe, economical, and practical alternative to pentazocine, especially in low-resource settings where use of an opioid or neuraxial options are not available or feasible.

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PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Aug 27, 2025
- Manual Googling: Jan 10, 2026
- iThenticate Software: Jan 12, 2026 (1%)

ETYMOLOGY: Author Origin

EMENDATIONS: 7

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **Aug 02, 2025**
Date of Peer Review: **Nov 07, 2025**
Date of Acceptance: **Jan 14, 2026**
Date of Publishing: **May 01, 2026**