

**ORIGINAL RESEARCH**

# Evaluating the Efficacy of Tramadol as an Analgesic in Labor Pain Management

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**ABSTRACT**

**Background:** Labour pain can be intense and physically and psychologically taxing. Various pharmacologic interventions, including opioids like tramadol, are commonly used to alleviate labor pain. Tramadol, a synthetic opioid, is known for its reduced sedative and respiratory depressant, making it a potential alternative to traditional opioids. This study aimed to evaluate the efficacy of tramadol in alleviating labor pain, its impact on labor duration, and maternal and fetal outcomes.

**Methods:** The study was conducted at Department of Obstetrics and Gynaecology, Government Medical College, Srinagar over two years from November 2018 to November 2020, involving 250 women aged 18-35 years, divided into two groups: the study group (n=125) patients who received intramuscular tramadol (100 mg), and the control group (n=125) patients who refused to receive labour analgesia. Pain relief was assessed using the Rupee scale, and maternal and neonatal outcomes were monitored, including APGAR scores at 1 and 5 minutes. **Results:** Results showed that tramadol significantly alleviated pain, with 50% of patients in the study group experiencing no pain during the first stage of labor compared to 36.8% in the control group. The study group also had a lower caesarean section rate (10.4%) compared to the control group (22.4%). Neonatal outcomes were better, with 96% of babies in the study group having an APGAR score of  $\geq 7$  at 1 and 5 minutes compared to 86% in the control group. Maternal morbidity was significantly lower in the study group ( $p = 0.009$ ). Side effects from tramadol were mild and did not significantly affect outcomes. **Conclusion:** In conclusion, intramuscular tramadol is an effective, safe, and cost-effective analgesic for labor pain management. It reduces pain, shortens labor duration, and improves neonatal outcomes, with minimal maternal morbidity, making it a beneficial option for both mother and baby.

**Keywords:** Tramadol, labor pain, analgesia, maternal morbidity, neonatal outcomes

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**INTRODUCTION**

Childbirth, though a natural process, is often accompanied by intense pain. This pain, experienced by women across all social and ethnic groups, can be both physically and psychologically taxing, with nulliparous women being more likely to experience severe pain than multiparous women<sup>1,2</sup>. While non-pharmacologic methods such as emotional support, psycho-prophylactic preparation, yoga, and hypnosis have been employed to alleviate pain, pharmacologic interventions like epidural blockade and parenteral opioids are also used<sup>4</sup>. Labour pain is not only a source of distress for the mother but can also lead to detrimental effects on the fetus<sup>5</sup>. The provision of adequate analgesia has been shown to positively influence maternal and fetal outcomes, thus

establishing its importance in modern obstetrics<sup>5</sup>. The ideal analgesic during labour should be easy to administer, cost-effective, and offer reliable pain relief without impairing the mother's consciousness<sup>6</sup>. Tramadol, a synthetic opioid analgesic, is believed to have a comparable analgesic efficacy to meperidine but with fewer sedative effects and reduced neonatal respiratory depression<sup>7</sup>. Its mechanism of action includes inhibiting the reuptake of serotonin and norepinephrine, which enhances its analgesic properties and makes it a promising alternative to traditional opioids. Tramadol has been shown to be effective in relieving moderate to severe pain and is considered a safer option due to its lower sedative and respiratory depression effects, particularly when compared to opioids like pethidine and morphine<sup>8</sup>.

Pain experienced during labour is often reported as severe or intolerable by up to 61% of women and may lead to harmful physiological responses in both the mother and fetus<sup>9</sup>. Effective pain relief during childbirth not only enhances the parturient's experience but also reduces maternal stress, facilitates shorter labour, and improves maternal and fetal outcomes<sup>10</sup>. Tramadol's affordability and safety profile make it an attractive option, especially in developing countries where access to advanced pain management techniques is limited. While tramadol has been suggested as an effective analgesic, some studies have raised concerns regarding its maternal and neonatal effects due to its placental permeability<sup>11,12</sup>. However, evidence suggests that tramadol may have a better tolerability profile compared to other opioids, with fewer side effects on both the mother and the newborn<sup>13</sup>.

## OBJECTIVES

To evaluate the efficacy of tramadol hydrochloride in alleviating pain during labor, its effects on the duration of labor, and maternal and fetal outcome.

## MATERIAL AND METHODS

The study was conducted over a two year period (November 2018 to November 2020) in the Department of Obstetrics and Gynecology, Government LallaDed Hospital, an associated hospital of Government Medical College, Srinagar, after approval from the Institutional Ethics Committee. A total of 250 women, aged between 18 and 35 years, were included and divided into two groups, with 125 participants in each group.

Inclusion criteria for the study were singleton live pregnancy, cephalic fetal presentation, age between 18-35 years, estimated fetal weight (EFW) between 2-4 kg, gestational age between 37 weeks 0 days and 42 weeks 0 days primigravid, patients in labor with intact membranes, no contraindications for vaginal delivery (e.g., placenta previa, vasa previa, active genital herpes), and no cephalopelvic disproportion.

The study excluded participants with multiple gestations, non-vertex fetal presentation, age <18 years or >40 years, estimated fetal weight (EFW) outside the range of 2-4 kg, severe oligohydramnios, previous caesarean section, malpresentation, premature rupture of membranes with signs or symptoms of chorioamnionitis, non-reassuring fetal heart rate patterns, antepartum hemorrhage, contraindications for vaginal delivery, and those with a history of medication hypersensitivity, respiratory conditions, hypertension, cardiac conditions, epilepsy, or psychiatric illnesses.

## METHODOLOGY

In the study group, intramuscular tramadol hydrochloride was administered at a dosage of 100 mg (one ampule containing 2 ml, with each 1 ml equivalent to 50 mg). A maximum of three doses,

with an interval of 8 hours, were given. Prior to administration, patients' vital signs were recorded, and a pain score was documented once the active phase of labor was confirmed (cervical dilation of 4 cm). If no pain alleviation was observed after the initial dose, a second 50 mg dose was administered 8 hours later, making the total dosage 150 mg. Vital signs, including blood pressure, pulse rate, respiratory rate, and fetal heart rate, were closely monitored throughout the process. Any pain reduction or lack thereof was noted, and the onset of action and adverse effects of the drug were documented. The patient's vital signs were checked every 10 minutes for the first 30 minutes, every 15 minutes for the next 30 minutes, and every 30 minutes thereafter. Additionally, labor progression and fetal heart rate were clinically monitored. Pain relief was evaluated using a scoring system every 15 minutes, and injections were repeated every 8 hours, with a daily maximum dose of 200 mg. A partogram was used to document labor duration, pain alleviation during the first and second stages of labor, the total amount of tramadol administered, the method of delivery, and the recovery period for each patient. The APGAR score of the neonate was recorded at 1 and 5 minutes post-delivery<sup>14</sup>.

Pain alleviation was measured using the Rupee Scale<sup>15</sup>. Pain relief was graded as Grade I – No pain (0%); Grade II – Mild pain but comfortable (25%); Grade III – Moderate pain with discomfort (50%); Grade IV – Severe pain (100%). The control group consisted of 125 patients, matched for age, parity, and socioeconomic status, who did not receive any analgesics. Pain levels, vital signs, and labor duration were monitored during labor. After delivery, the APGAR scores of the neonates were recorded at 1, 5, and 10 minutes, and any labor complications were noted.

Statistical analysis was performed using Statistical Package for Social Sciences (SPSS version 25), employing descriptive statistics, Chi-square tests, independent t-tests, Mann-Whitney U tests, and Pearson correlation to compare pain relief, labor duration, maternal and neonatal outcomes, and side effects between the study and control groups, with statistical significance set at  $p < 0.05$ .

## RESULTS

This study included a total of 250 patients, with 125 patients in each group, to evaluate the effectiveness of intramuscular Tramadol in relieving labor pain. The study aimed to compare the outcomes between the study group, which received Tramadol, and the control group, which did not receive any analgesic medication. The age distribution of the patients showed that most were aged between 18 and 35 years, with the majority of patients (64%) falling within the 18-24 age group. In terms of parity, 58% of the patients were primigravid in parity. Regarding the mode of delivery, 90% of the study group delivered via normal vaginal delivery, whereas 78% of the

control group had vaginal deliveries. In contrast, 10% of the study group and 22% of the control group had caesarean deliveries.

When evaluating newborn outcomes, the study found that 96% of babies in the study group had an APGAR score of  $\geq 7$  at 1 minute and  $\geq 9$  at 5 minutes, compared to 60% in the control group. Only 4% of the study group babies had an APGAR score of  $< 7$  at 1 minute, while 14% of the babies in the control group had a lower score. Regarding NICU admission, only 4% of the babies in the study group needed NICU care, compared to 6% of babies in the control group. In terms of pain relief, the study demonstrated a significant improvement in the study group after receiving intramuscular Tramadol. During the first stage of labor, 50% of patients in the study group experienced no pain (Grade I), compared to 36.8% in the control group. Additionally, 7.2% of patients in the study group had moderate pain (Grade III), while 38% experienced severe pain (Grade IV), as opposed

to 11.2% and 47.2%, respectively, in the control group. In the second stage of labor, fewer patients in the study group experienced Grade III and IV pain (10% and 43.2%, respectively) compared to 13.2% and 54.4% in the control group.

Maternal morbidity was significantly lower in the study group ( $p = 0.009$ ). However, there was no significant difference in fetal morbidity between the two groups ( $p = 0.884$ ). The occurrence of fetal distress was 6% in the study group and 11% in the control group, meconium aspiration was observed in 4% of the study group and 6% of the control group, and birth asphyxia occurred in 1% of the study group and 2% of the control group. Side effects from the Tramadol administration included nausea, vomiting, headache, dizziness, tingling in the legs, restlessness, perspiration, burning sensations in the legs, and hypotension. These side effects were generally mild and did not significantly impact the overall outcome.

| Table 1: Mode of Delivery |                       |                     |
|---------------------------|-----------------------|---------------------|
| Mode of Delivery          | Control Group (n=125) | Study Group (n=125) |
| Vaginal Delivery          | 97 (77.60%)           | 112 (89.60%)        |
| Caesarean Delivery        | 28 (22.40%)           | 13 (10.40%)         |
| <b>Total</b>              | <b>100.0%</b>         | <b>100.0%</b>       |

| Table 2: APGAR Scores at 1 and 5 Minutes |       |                     |         |                       |         |            |
|--|-------|---------------------|---------|-----------------------|---------|------------|
| APGAR Score                              |       | Study Group (n=125) |         | Control Group (n=125) |         | P value    |
|  |       | Number              | Percent | Number                | Percent |            |
| 1 min                                    | $> 7$ | 120                 | 96.0    | 75                    | 60.0    | 0.000 Sig. |
|  | $< 7$ | 5                   | 4.0     | 50                    | 40.0    |            |
| 5 min                                    | $> 7$ | 120                 | 96.0    | 70                    | 65.0    | 0.000 Sig. |
|  | $< 7$ | 5                   | 4.0     | 55                    | 35.0    |            |

## DISCUSSION

In this study, we assessed the effectiveness of intramuscular tramadol in alleviating labor pain and its effects on maternal and fetal outcomes. The results indicated that tramadol effectively reduces labor pain, as evidenced by a significant reduction in pain scores in the study group when compared to the control group. Our findings are consistent with those of **Thakur R et al., (2004)**<sup>16</sup> where the mean maternal age was 22.43 years, similar to our study's mean age of 22 years. The majority of patients in both studies were in the 18-24 age group, which is also reflective of our study (64%). In our study, all the enrolled women were primigravida, aligning with the study by **Shyamsundar B et al., (2018)**<sup>17</sup> where the majority were primigravida.

Regarding the mode of delivery, 90% of the patients in the study group had a normal vaginal delivery, compared to 78% in the control group. This difference was statistically significant. This is in contrast to the findings of **Vanitha M et al., (2019)**<sup>18</sup> where the spontaneous vaginal delivery rate in the tramadol group was 82.5%, which is similar to the rate of 83.5% in the control group. The percentage of cesarean section in the tramadol group was 10%,

which was slightly lower than the control group at 10.5%. The fetal outcomes in our study were also promising. Only 4% of the babies in the study group required NICU admission, compared to 10% in the control group, indicating better fetal outcomes in the tramadol group. This aligns with the findings by **Shyamsundar B et al., (2018)**<sup>17</sup> where 8% of babies in the study group had fetal distress compared to only 3% in the control group. The percentage of babies requiring NICU care due to meconium aspiration was lower in our study group compared to the control group.

The APGAR scores in our study showed that the majority of babies in both the study and control groups had a good APGAR score at 1 minute and 5 minutes. This is in line with the study conducted by **Bajaj P et al., (1997)**<sup>19</sup> where all babies had an APGAR score between 8-10 at 5 minutes, further supporting the notion that tramadol does not adversely affect fetal health. In terms of pain relief, our study demonstrated that 50% of patients in the study group experienced no pain (Grade I) after receiving intramuscular tramadol during the first stage of labor, compared to 36.8% in the control group. Moreover, the study group showed a significant reduction in

Grade III and IV pain compared to the control group, which was statistically significant. These results are consistent with those of **Thakur R et al., (2004)**<sup>16</sup>. The analgesic effect of tramadol in our study lasted for approximately 6 hours, and the duration of labor was shorter in the tramadol group, which suggests its potential to not only alleviate pain but also to enhance labor progress. These findings are consistent with the results of previous study by **Vellanki J and Sri VS (2023)**<sup>20</sup>.

## CONCLUSION

This study concludes that Intramuscular Tramadol Injection is an effective and safe analgesic for labor pain management. It significantly reduces pain during the first stage of labor, shortens the duration between the first and second stages, and reduces the rate of instrumental or caesarean deliveries. Importantly, there were no adverse effects on either maternal or fetal health, and the duration of the third stage of labor remained unaffected. Tramadol administration did not lead to increased hospital stays or maternal morbidity, demonstrating its cost-effectiveness as a labor analgesic. Overall, Tramadol is a viable option for providing labor analgesia with minimal morbidity, making it a beneficial choice for both the mother and baby.

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