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Original Research Article

Comparison of butorphanol-drotaverine versus tramadol-drotaverine as labour analgesics: an observational comparative study

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ABSTRACT

Background: Labour pain is a significant challenge in obstetric care, with effective pain management being essential for maternal well-being and labor outcomes. Epidural analgesia, the gold standard, is often inaccessible in resource-limited settings. Parenteral opioids like butorphanol and tramadol, combined with drotaverine, may provide an effective, low-cost alternative. To compare the effectiveness of butorphanol-drotaverine versus tramadol-drotaverine as labour analgesics in terms of maternal pain relief, labour outcomes and fetal outcomes.

Methods: This observational, prospective, single-center study was done on 300 low-risk primigravid women in active labor where Butorphanol 1 mg+Drotaverine 40 mg was given to 150 patients (Group B) and Tramadol 100 mg+Drotaverine 40 mg was given to another 150 patients (Group T). Maternal pain was assessed using the Visual Analog Scale (VAS) at various time intervals. Labor progress, mode of delivery and side effects were monitored, along with fetal outcomes including Apgar scores and NICU admissions.

Results: Both analgesic combinations provided effective pain relief, with Butorphanol providing quicker pain relief while as more sustained pain reduction was obtained with Tramadol. However, there were no significant differences in labor duration, mode of delivery or neonatal outcomes. Nausea was more common in the Tramadol group. Both drugs were well-tolerated, with minimal adverse effects.

Conclusions: Both Butorphanol and Tramadol are effective for labor analgesia, with Butorphanol providing faster pain relief. These opioids offer a cost-effective alternative to epidural analgesia, especially in resource-limited settings, ensuring access to pain relief for all women during labor.

Keywords: Butorphanol, Drotaverine, Fetal outcomes, Labor analgesia, Maternal outcomes, Pain relief, Tramadol

INTRODUCTION

Labour pain is a complex and intensely individual experience, influenced by physiological, psychological, social and cultural factors. It remains one of the most challenging aspects of obstetric care. The intensity of pain experienced during labour varies significantly among women and can be affected by emotional, motivational, cognitive and cultural circumstances. Nulliparous women

(those giving birth for the first time) generally experience more severe pain compared to multiparous women (those who have given birth previously).

Effective pain management is critical not only for improving maternal comfort but also for reducing the potential neuropsychological consequences of unrelieved pain, such as postnatal depression and post-traumatic stress disorder (PTSD).¹ Additionally, severe, unrelieved pain during labour has been associated with adverse

maternal physiological responses, including elevated cortisol levels, increased sympathetic nervous system activity and impaired uteroplacental perfusion, which can affect fetal well-being.

The experience of labour pain is multifactorial and is caused by mechanical and chemical stimuli, including uterine contractions, cervical dilation and stretching of the pelvic tissues. These stimuli are transmitted through complex neural pathways involving the cervix, uterus and pelvic structures, with pain perception varying from the visceral pain of the first stage of labour to the more localized somatic pain in the second stage.² The pain in the first stage is often described as diffuse, cramping and poorly localized, primarily carried by unmyelinated C fibers. In contrast, the pain in the second stage of labour is more localized, sharp and intense, carried by myelinated A-delta fibers and involving the perineum, vagina and lower back areas.³

Over the years, several techniques for labour analgesia have been developed, ranging from non-pharmacological methods like transcutaneous electrical nerve stimulation (TENS), relaxation and breathing exercises to pharmacological interventions, including opioids and regional anaesthesia. The historical development of obstetric anaesthesia began with James Young Simpson's introduction of ether in the 19th century, a controversial move at the time, followed by significant contributions from pioneers like John Snow, who administered chloroform to Queen Victoria during childbirth in 1853.⁴ Despite these advances, the effective management of labour pain remains an area of ongoing research, with a particular focus on minimizing the risks to both the mother and the fetus.

Pharmacological options for pain relief during labour include systemic opioids, regional analgesia and local anaesthetic techniques. Opioids, such as Butorphanol and Tramadol, are commonly used for their effective analgesic properties. These drugs work by interacting with opioid receptors (μ , κ and δ) in the central nervous system and peripheral tissues, providing significant pain relief. However, opioid use during labour is not without risks, including potential respiratory depression, sedation and effects on fetal heart rate and neonatal respiratory function.⁵ Although both Butorphanol and Tramadol are effective analgesics, their side effects and comparative efficacy in combination with other drugs, such as Drotaverine, remain subjects of investigation.

Drotaverine, a smooth muscle relaxant, has been shown to enhance the efficacy of pain relief during labour, particularly when combined with other analgesics. However, there is limited data comparing the combination of Butorphanol-Drotaverine and Tramadol-Drotaverine for optimal labour analgesia. Both of these combinations are believed to work synergistically to improve pain relief while potentially reducing the dose of each drug required, thus minimizing side effects.

Need for the study

Pain is a significant source of fear for many women during labour, whether they are giving birth for the first time or have had previous pregnancies. Modern women often seek to avoid the intense pain associated with labour. Although epidural analgesia is considered the gold standard for pain relief, its use remains limited in countries like India due to factors such as the need for an anaesthesiologist, high costs and the requirement for continuous monitoring. On the other hand, opioid analgesics offer effective pain relief with minimal side effects. They are relatively easy to administer, cost-effective, require little monitoring and do not demand specialized equipment or personnel. This study aims to promote the use of opioid analgesics for labour pain management, especially in primary and secondary healthcare settings, where the majority of low-risk pregnancies are managed. Widespread use of these drugs could help reduce unnecessary caesarean sections, which are a growing concern in obstetrics and also decrease the morbidity associated with both unnecessary surgeries and unrelieved labour pain.

Aims and objectives

To compare the effectiveness of butorphanol-drotaverine versus tramadol-drotaverine as labour analgesics in terms of maternal pain relief, labour outcomes (including incidence of instrumental and caesarean delivery and duration of labour) and fetal outcomes (measured by APGAR scores at 1 and 5 minutes and NICU admissions) between the two groups.

METHODS

This was a single-center, hospital-based, observational prospective comparative study conducted at the Department of Obstetrics and Gynaecology, Government Medical College (GMC) Srinagar. The study was carried out from 1st October 2018 to 31st October 2020.

The study included 300 low-risk primigravid women in active labor, divided into two groups. Group B consisted of 150 women who received a combination of Butorphanol (1mg intramuscularly) and Drotaverine (40mg intramuscularly), while Group T comprised 150 women who received a combination of Tramadol (100mg intramuscularly) and Drotaverine (40mg intramuscularly) for labor analgesia.

Inclusion criteria

Primigravid women with a singleton live fetus and satisfactory admission CTG. Gestational age of 37 completed weeks. Vertex presentation with no evidence of cephalopelvic disproportion (CPD). Women in the active phase of labor, defined as cervical dilation >4 cm with regular contractions (≥ 3 contractions in 10 minutes, each lasting 35-40 seconds).

Exclusion criteria

History of hypersensitivity to the study drugs. Pre-existing medical conditions such as heart disease, chronic hypertension, epilepsy, respiratory and renal diseases. Obstetric complications including intrauterine growth restriction (IUGR), oligohydramnios, antepartum hemorrhage, multiple gestations, cephalopelvic disproportion, gestational diabetes and pregnancy-induced hypertension.

After obtaining written informed consent, 300 eligible primigravid women in the active phase of labor were randomly assigned to receive one of the two analgesic regimens:

Group B (Butorphanol+Drotaverine)

150 women received 1mg butorphanol intramuscularly and 40 mg drotaverine intramuscularly at the start of active labor.

Group T (Tramadol+Drotaverine)

150 women received 100 mg Tramadol intramuscularly and 40 mg Drotaverine intramuscularly at the start of active labor.

Both analgesics were administered as per the clinical decision made by the attending consultant or team. The following maternal and fetal parameters were observed at regular intervals. Maternal pain was assessed using the visual analogue scale (VAS) at 15 minutes, 30 minutes, 45 minutes, 1 hour and hourly thereafter until delivery. The VAS was a 10 cm line, where 0 represented no pain and 10 represented the worst possible pain. Pain was categorized as (i) 0-3, minimal pain; 4-6, mild pain; 7-8, moderate pain; 9-10, severe pain. Maternal pulse rate, blood pressure and respiratory rate were monitored at the time of drug administration, at 30 minutes, 1 hour and hourly thereafter until delivery.

The progress of labor was assessed using a partogram, including cervical dilation, descent of the fetal head and frequency of uterine contractions. Mode of delivery (vaginal delivery, instrumental delivery or cesarean section) was recorded for each participant. Side effects such as nausea, vomiting, drowsiness, palpitations, hypersensitivity reactions, respiratory distress and post-partum hemorrhage (PPH) were monitored.

Fetal heart rate was recorded before and after the administration of labor analgesia. Fetal well-being was assessed using the Apgar score at 1 minute and 5 minutes after birth. Intermittent cardiotocographic (CTG) monitoring was performed to assess fetal heart rate patterns. Neonatal depression, need for resuscitation and NICU admission were evaluated. 150 women in Group B received a single dose of 1mg Butorphanol intramuscularly at the start of the active phase of labor. 150

women in Group T received a single dose of 100 mg Tramadol intramuscularly at the start of the active phase of labor. All 300 patients received 40 mg intramuscular Drotaverine at the onset of the active phase of labor as a cervical dilator. Naloxone was available as an antidote in case of any respiratory depression in neonates due to Butorphanol or Tramadol administration. Maternal and neonatal outcomes were followed up until discharge from the hospital.

Data obtained was entered into a spreadsheet (Microsoft Excel) and analyzed using SPSS version 20.0. Continuous variables were expressed as means with standard deviations, while categorical variables were summarized as percentages. The statistical significance of differences between the two groups was assessed using Student's independent t-test for continuous variables and Chi-square test or Fisher's exact test, as appropriate, for categorical variables. A p value of less than 0.05 was considered statistically significant. The results were presented graphically using bar and line diagrams.

RESULTS

In this study, the effects of butorphanol and tramadol on pain relief, maternal and fetal outcomes and side effects during labor were compared. The mean age of subjects in the butorphanol group was 24.4 ± 3.65 years, while the mean age in the tramadol group was 24.7 ± 3.74 years. The difference in age between the two groups was not statistically significant. Similarly, the mean gestational age in the Butorphanol group was 38.9 ± 0.901 weeks and in the Tramadol group, it was 39.1 ± 0.758 weeks, with no significant difference observed between the groups.

Before drug administration, the mean visual analog score (VAS) was 9.31 ± 1.023 in the Butorphanol group and 9.35 ± 0.882 in the Tramadol group, which showed no statistically significant difference. After the administration of the drugs, the VAS scores dropped over time in both groups, indicating effective pain relief. However, the VAS scores in the Butorphanol group were lower compared to the Tramadol group at 15 minutes (5.37 versus 9.23), 30 minutes (4.13 versus 8.39), 45 minutes (3.54 versus 6.01) and 1 hour (3.10 versus 4.09) with a statistically significant difference ($p < 0.05$). At 4 hour, 5 hour and 6 hour Tramadol group showed better pain relief than Butorphanol with a VAS score of 3.19 compared to 4.07, 3.39 compared to 4.15 and 3.67 compared to 4.75 ($p < 0.05$). The comparison of minimum VAS (representing maximum pain relief) showed no statistically significant difference between the groups, with butorphanol at 3.10 and tramadol at 3.05 ($p = 0.321$).

When analyzing the effect of age on pain relief, no statistically significant differences in VAS before drug administration or at maximum pain relief were found in both the butorphanol and tramadol groups. Similarly, gestational age did not significantly affect pain relief in either group, with VAS scores before drug administration

and at maximum pain relief being comparable across different gestational age categories. The mean duration of active labor was 219.6 minutes (SD 23.72) in the butorphanol group and 221.3 minutes (SD 21.17) in the tramadol group, with no significant difference between the two groups. Regarding the mode of delivery, the most common mode in both groups was vaginal delivery, which occurred in 90.7% (136/150) of the Butorphanol group and 90% (135/150) of the Tramadol group. The next most common was cesarean section (LSCS), occurring in 6.7% (10/150) of the Butorphanol group and 6% (9/150) of the Tramadol group. There were also instances of instrumental vaginal delivery, but the difference between the groups was minimal.

In terms of side effects, nausea was reported more frequently in the Tramadol group (9.3%, 14/150) compared to the Butorphanol group (3.3%, 5/150) and this difference was statistically significant ($p=0.008$). Vomiting occurred in 4.7% (7/150) of patients in the Tramadol group and 1.3% (2/150) in the Butorphanol group, although this difference was not statistically significant. Both groups had a similar incidence of drowsiness (1.3% in the Butorphanol group and 0.7% in the Tramadol group) and this was not statistically significant.

The mean maternal heart rate at the time of drug administration was 144.31 bpm in the Butorphanol group and 144.93 bpm in the Tramadol group, with no significant differences observed at subsequent intervals. Additionally, there was no significant difference in maternal blood pressure (systolic, diastolic) or mean arterial pressure at any time points, except at 30 minutes post-injection, where systolic and diastolic blood pressure in the Tramadol group were statistically significantly higher than in the Butorphanol group ($p = 0.001$ and $p=0.002$, respectively). Similarly, maternal respiratory rate showed no statistically significant differences between the groups.

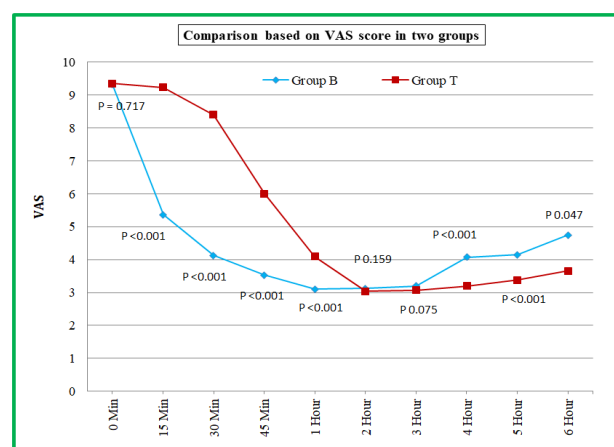


Figure 1: Comparison based on VAS score in two groups.

The neonatal outcomes were generally favorable in both groups with insignificant differences in the APGAR scores between the two groups. The mean APGAR score at 1 minute was 8.31 in the Butorphanol group and 8.14 in the Tramadol group, while at 5 minutes, the scores were 8.66 for Butorphanol and 8.63 for Tramadol. The differences in APGAR scores were not statistically significant. Only one infant in the Butorphanol group (0.7%) required NICU admission, while there were no NICU admissions in the Tramadol group.

In conclusion, both Butorphanol and Tramadol were effective in providing pain relief during labor, with Butorphanol leading to a quicker pain relief while more sustained reduction in pain was obtained with Tramadol. There were no significant differences in labor duration, mode of delivery or neonatal outcomes between the two groups. However, nausea was more prevalent in the Tramadol group. Both drugs were found to have a similar safety profile, with minimal adverse effects overall.

Table 1: Mean age and mean gestational age of the patients.

	Group B	Group T	P value
Mean age of patients	24.4±3.65	24.7±3.74	0.628
Mean Gestational age	38.9±0.901	39.1±0.758	0.125

Table 2: Comparison based on maternal side effects in two groups.

Side effects	Group B		Group T		P value
	No.	%	No.	%	
Nausea	5	3.3	14	9.3	0.032*
Vomiting	2	1.3	7	4.7	0.091
Drowsiness	2	1.3	1	0.7	0.562
PPH	1	0.7	2	1.3	0.562
Palpitation	0	0.0	0	0.0	-
Hypersensitivity	0	0.0	0	0.0	-
Respiratory distress	0	0.0	0	0.0	-
Foetal tachycardia	0	0.0	0	0.0	-

*:statistically significant

Table 3: Outcome.

	Group B	Group T	P value
Duration of labour	276.9 (SD=26.9)	279.1 (SD=22.8)	0.924
NVD	136 (90.7%)	135 (90%)	0.796
Instrumental VD	4 (2.7%)	6 (4%)	
LSCS	10 (6.7%)	9 (6%)	
Apgar at 1 min	8.31 (SD=0.85)	8.14 (SD=0.851)	0.075
Apgar at 5 min	8.66 (SD=0.6)	8.63 (SD=0.661)	0.648
NICU admission	1 (0.7%)	0 (0%)	1

DISCUSSION

Our study aimed to compare the efficacy of the combination of Tramadol-Drotaverine and Butorphanol-Drotaverine as labor analgesics, focusing on pain scores, fetomaternal outcomes and side effects. A total of 300 patients were included in the study, with 150 women receiving tramadol (100 mg) and drotaverine (40 mg) and the other 150 receiving butorphanol (1 mg) and drotaverine (40 mg) at the start of the active stage of labor.

In terms of patient demographics, the mean age of patients in Group B (Butorphanol) and Group T (Tramadol) was 24.4 ± 3.65 years and 24.7 ± 3.74 years, respectively, the difference was statistically insignificant (0.628). Our study found that age did not significantly affect the pain visual analog scale (VAS) scores, corroborating the findings of Niven et al, Gijsbers et al who also reported no significant relationship between age and labor pain intensity.⁶ The mean gestational age in our study was 38.9 ± 0.901 weeks and 39.1 ± 0.758 weeks in Group B and Group T, respectively. These values were similar to those reported by Jamwal et al, with mean gestational ages of 38.8 ± 1 weeks and 38.7 ± 1 weeks in their study.⁷ Our study did not include any preterm or post-term pregnancies and gestational age did not appear to have an effect on VAS pain scores, supporting the findings of other studies on term pregnancies.

The pre-drug administration VAS scores were 9.31 (SD=1.023) for the Butorphanol group and 9.35 (SD=0.882) for the Tramadol group, indicating severe pain, with no statistically significant difference (p-value 0.717). After drug administration, the pain scores at 15 minutes, 30 minutes, 45 minutes and 1 hour were significantly lower in the Butorphanol group compared to the Tramadol group. This suggests that Butorphanol provided quicker pain relief than Tramadol in the early stages of labor.

This observation is consistent with studies by Maduska et al, Hajghassemali et al and Atkinson et al, where significant pain relief was noted within 15 minutes and 30 minutes post-Butorphanol administration.^{8,9} In addition, Halder et al and Agarwal et al also reported pain reduction within 15 minutes, with the nadir of pain relief reached at

1-2 hours post-administration.¹⁰ Maximum pain relief (i.e., the lowest VAS score) was achieved at 1 hour in the Butorphanol group (VAS 3.1) and at 2 hours in the Tramadol group (VAS 3.05). The comparison of minimum VAS scores showed no statistically significant difference between the groups (p value 0.321), indicating that the analgesic efficacy of Butorphanol and Tramadol is comparable in terms of overall pain relief. However, pain relief duration differed significantly, with Tramadol providing prolonged relief, particularly at 4-, 5- and 6-hours post-administration (p value 0.001). These findings are in agreement with Ahluwalia et al study, which demonstrated that Butorphanol's analgesic effects waned at 4 hours, whereas Tramadol had a peak effect between 3-4 hours.¹¹

The mean duration of the active stage of labor in our study was 219.6 ± 23.72 minutes in the Butorphanol-Drotaverine group and 221.3 ± 21.17 minutes in the Tramadol-Drotaverine group, with no statistically significant difference (p-value 0.506). This is consistent with the findings of Srivastava et al who reported a mean duration of 224 minutes for the active stage of labor following intramuscular administration of Drotaverine.¹²

In terms of delivery outcomes, 90.7% of patients in Group B and 90.0% of patients in Group T had a normal vaginal delivery, with rates of instrumental vaginal delivery and LSCS being 2.7% and 6.7%, respectively, in the Butorphanol group and 4% and 6.0%, respectively, in the Tramadol group. There was no statistically significant difference in delivery mode between the two groups (p-value 0.796). Our findings align with the WHO global survey (2007-2008), which reported LSCS rates of 17.8% in India, but the lower rates in our study can be attributed to the exclusion of high-risk pregnancies.

Regarding side effects, nausea was more prevalent in the Tramadol group (9.3%) compared to the Butorphanol group (3.3%) and this difference was statistically significant (p value 0.032). Similar findings were reported by Tripti et al, Jyoti et al, Khooshideh et al, Shahriari et al and Bajaj et al where the incidence of nausea was notably higher in the Tramadol group.¹³⁻¹⁵ Vomiting was reported in 4.7% of patients in the Tramadol group and 1.3% in the Butorphanol group, but this difference was not statistically

significant (p value 0.091). Previous studies by Kuti et al, Tripti et al also reported similar rates of vomiting in patients receiving Tramadol for labor analgesia.^{13,16,17}

Drowsiness was noted in 1.3% of patients in the Butorphanol group and 0.7% in the Tramadol group and this difference was not statistically significant (p value 0.562), which is consistent with studies by Tripti et al, Jyoti et al and Thakur et al, Patidar et al, who reported drowsiness rates of 1% and 2%, respectively, after Tramadol administration.^{13,17} In terms of neonatal outcomes, the mean 1-minute APGAR scores were 8.31 in the Butorphanol group and 8.14 in the Tramadol group, while the mean 5-minute APGAR scores were 8.66 and 8.63, respectively, with no significant difference between the groups. These results are similar to those reported by Jamwal et al, and Lakshman et al, where the 1-minute and 5-minute APGAR scores were within the normal range.^{7,18}

Only one baby in the butorphanol group required NICU admission for observation due to meconium-stained liquor and no infants required Naloxone administration, as there was no evidence of respiratory depression. In terms of vital parameters, no significant changes in pulse rate were observed in either group after drug administration. There was a slight decrease in systolic blood pressure and respiratory rate in both groups, but these changes were within physiological ranges and not statistically significant. These findings are consistent with studies by Lallar et al, and Andey et al, which found no significant change in vital parameters following Tramadol administration.^{19,20} Similarly, Atkinson et al, observed a slight decrease in systolic blood pressure and respiratory rate after Butorphanol administration.⁹

CONCLUSION

In modern obstetrics, pain relief during labor has become essential, with epidural analgesia widely used in developed countries and some resourceful centres in India. However, its high cost and dependence on specialized infrastructure make it less accessible in resource-poor settings. In such settings, parenteral opioids like Butorphanol and Tramadol offer an effective, low-cost alternative, providing good pain relief with minimal side effects and no significant risk of dependency. These opioids can be stored and administered without special arrangements, making them suitable for remote areas. If prioritized in healthcare policies, both Butorphanol and Tramadol can ensure that no woman is deprived of pain relief during labor, regardless of her location or resources.

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