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Original Research Article

Tramadol – A wonder drug in women with labour pain

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ABSTRACT

Background: Pain management during labour is an essential part of good obstetric care. Though this severe pain during labour is not life-threatening, it can have physiological and neuropsychological consequences. Adequate analgesia during labour is a benefit for the mother, has a positive influence on the course of labour and the state of the new born child. The ideal analgesic in obstetrics should have potent opiate-like analgesic efficacy with minimal side effects. Tramadol can be used as a basic analgesic for the treatment of patients with moderate to severe pain. Parenteral tramadol during labour was proven to have no negative effects on the baby or the process of labour.

Materials and Methods: The study was conducted for a period of one year from April 2022 to March 2023 in the Department of obstetrics and Gynaecology, Gandhi Medical College and Hospital, Hyderabad after approval from Institutional Ethics Committee. Total of 500 parturient of age group 18 to 35 years were divided into 2 groups, control and study groups 250 participants each. The drug utilized was Intramuscular Tramadol Hydrochloride at a dosage of 1 ampule containing 2 ml, where 1 ml is equivalent to 50 mg.

Results: It is observed that there was a significant decrease in the degree of pain when compared to control group after giving Intramuscular Tramadol injection. And the majority of the patients had good neonatal outcomes and no maternal complications and reduced the duration of labour. In the study group 10% and 43.2% of patients, whereas 13.2% and 54.4% of patient in control group had Grade III and Grade IV pain, which was statistically significant.

Conclusion: Intramuscular Tramadol Injection is safe for both mother and baby, effective and shortens the duration of labour period.

1. Introduction

During childbirth, the pain and misery are severe, frequently intolerable, and occasionally unbearable. It is characterized by regular, painful uterine contractions that increase in frequency and intensity and are associated with progressive cervical effacement and dilatation. The Utero placental blood flow is reduced by 25% during difficult labour. Good analgesia stops the pain that is caused by hyperventilation and hypocapnia, both of which can be severe enough to result in tetany during difficult labour. Obstetrical analgesia is a crucial component of contemporary obstetrics since it benefits the mother and has a good impact on the progression of labour and the condition of the new born child. The mother benefits from enough analgesia during labour, and it also benefits the baby and the way that labour progresses. [1,2]

An ideal analgesic should be simple to deliver, shouldn't impair the parturient state of consciousness, and should offer reversible, predictable, and effective analgesia. It shouldn't interfere with uterine contractions and allow the parturient to ambulate, at least in the early stages of labour. It shouldn't cause cardiorespiratory depression in the foetus

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or be hazardous to the mother. The analgesic efficacy of tramadol, a mild opioid drug, it has less sedative impact and less neonatal respiratory depression.[3]

Tramadol, a synthetic counterpart of codeine, is a centrally acting opioid analgesic with a low affinity for opioid receptors. It blocks the reuptake of serotonin and norepinephrine, strengthening the inhibitory effects on spinal cord pain transmission. It has been demonstrated to be efficient, well-tolerated, and very valuable in treating a number of painful disorders (Step II of the World Health Organization Ladder), where treatment with potent opioids is not necessary.[4] Compared to equivalent analgesic doses of potent opioids, tramadol is less addictive.[5] It has a low likelihood of abuse. The analgesic potency of 100 mg of tramadol intravenously is the same as that of 10 mg of morphine.[6] Patients with moderate to severe pain can be treated with tramadol as a primary analgesic.[7]

Parenteral Tramadol during labour was proven to have no negative effects on the baby or the process of labour. It had no inhibiting effects on the respiratory center.[8] Tramadol is well tolerated in short-term usage, with dizziness, nausea, vomiting, drowsiness, dry mouth, and sweating being the main adverse effects, according to a study done to understand its dynamic and pharmacokinetic features and therapeutic potential. When tramadol was infused for pain management during labour, respiratory depression was seen in a small number of individuals, although it did not affect new borns.[9]

In the present study, the effectiveness of Injectable Tramadol hydrochloride as a labour analgesic, its impact on the duration of labour, as well as its effects on the mother and new born, were investigated.

2. Aim of the Study

1. To study the efficacy of Intramuscular tramadol hydrochloride on Primigravida and Multigravida in terms of pain alleviation during labour.
2. To study the drug affects on the duration of labour.
3. To study the drug affects on the mother and the baby.

3. Materials and Methods

3.1. Type of the study

3.2. Cross sectional study

The study was conducted for a period of one year from April 2022 to March 2023 in the Department of Obstetrics and Gynaecology, Gandhi Medical College and Hospital, Hyderabad after approval from Institutional Ethics Committee. Total of 500 parturient of age group 18 to 35 years were divided into 2 groups, control and study groups 250 participants each. Intramuscular tramadol 100 mg was administered to the study group, while the control group did not receive any painkillers or analgesics. The patient was properly evaluated before the method was applied, paying close attention to their obstetric history.

The only drug utilized was Intramuscular Tramadol Hydrochloride at a dosage of 1 ampule containing 2 ml, where 1 ml is equivalent to 50 mg which is given upto maximum of 3 doses with interval of 8hours. After taking informed consent, participants in the late latent period (i.e., with cervical dilatation of 2- 3 cm) were enrolled in this study. Individuals had given their informed consent and met the inclusion and exclusion requirements.

250 patients in whom Injection Tramadol was given were included in study group I. Prior to giving the patient the medication, the patient's vital signs were taken and a pain score was documented once the active phase of labour had been confirmed. If no evidence of pain reduction were seen after receiving a 50 mg Injection Tramadol intramuscularly, the dose was repeated 12 hour later (making the total dose 100 mg). Blood pressure, respiration rate, pulse rate, and foetal heart rate were all monitored. The patient was instructed to let the doctor know as soon as their pain started to lessen or even if there was no pain alleviation at all. The drug's start of action and any negative effects were noted. For the first half hour, vital signs were checked every 10 minutes; for the second, they were checked every 15 minutes; and for the third, they were checked every 30 minutes. Clinical monitoring was done of both labour progress and foetal heart rate. Every 15 minutes, analgesia was evaluated using a score system, and injections were repeated every 3 to 4 hours with a daily maximum of 400 mg. Intermittently, the patient's degree of awareness, alertness, and psychological distress were assessed through conversation. With the aid of a partogram, the length of labour, the level of pain alleviation during the first and second stages, the total amount of Injection Tramadol administered, the method of delivery, and the recovery period for each patient were observed and documented. Once the neonate was delivered, the APGAR score was recorded at intervals of 1 and 5. 250 patients from the same age, parity, and socioeconomic position were included in the group 2 control group. Pulse rate, blood pressure, respiration rate, level of pain, and labour time were all examined and noted as the labour progressed. After birth, the neonate's APGAR score was recorded at intervals of one minute, five minutes, and ten minutes. The type of birth and complications during labour were noted.[10]

3.3. Inclusion criteria

1. Singleton live gestation
2. Fetus in cephalic presentation
3. Age between 18-35 years
4. EFW between 2-4 kg
5. Gestational age between 37 weeks 0 days 42 weeks 0 days.
6. Patients who are not in labor with intact membranes

7. Patients with no contraindications for vaginal delivery (placenta previa, vasa previa, active genital herpes)
8. Patients with no cephalo-pelvic disproportion.

3.4. Exclusion criteria

1. Multiple gestations
2. Non-vertex presentation
3. Age <18 years and >40 years
4. EFW >4kgs
5. EFW <2kgs
6. Severe oligohydramnios
7. Previous caesarean section
8. Mal-presentation
9. Premature rupture of membranes with signs and Symptoms of chorioamnionitis
10. Non-reassuring fetal heart rate pattern
11. Antepartum haemorrhage
12. Contra indications for vaginal delivery.
13. History of medication hypersensitivity, respiratory diseases, hypertension, cardiac conditions, epilepsy, and psychiatric illnesses.

A Rupee Scale was used to measure the level of pain alleviation.[11] The degree of pain relief was expressed as % of the whole rupee.

The degree of pain was graded as–>

1. Grade-I no pain – 0,
2. Grade-II is mild pain but comfortable – 25%,
3. Grade-III is moderate pain with discomfort – 50%
4. Grade-IV is severe pain.

4. Results

In this study, 250 patients of various ages were examined to determine the effectiveness and safety of Injection Tramadol in relieving labour pain as well as its patient side effects. This was contrasted with the control group, which consisted of 250 patients and did not receive any analgesic medication.

Inj.Tramadol was given at a dosage of 1 ampule containing 2 ml, where 1 ml is equivalent to 50 mg which is given upto maximum of 3 doses with interval of 8 hours to know the efficacy of the drug and it's effects on maternal and fetal outcome.

The age distribution of the patients is shown in Figure 1. The patients were all between the ages of 15 and 35. Most of the patients in both groups were between the ages of 20 and 24.

In our study group, the majority of patients (64%) belong to the 18-24 yrs. Age group, the youngest being 18 years and the oldest being 36 years.

Out of the total study group women, 290 were Primigravida (58%) and 210 were Multigravida (42%).

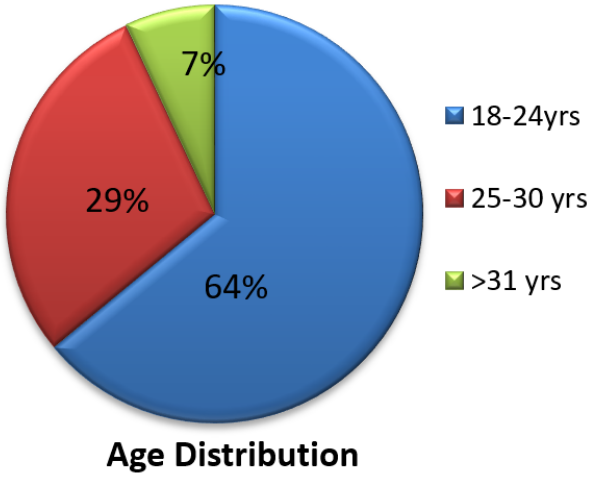

Figure 1: Distribution of the patients according to age group

Table 1: Distribution of the patients according to parity

Parity	No. of patients (n=500)	Percentage
PRIMI	290	58%
MULTI	210	42%
Total	500	100%

Table 2 depicts the modes of delivery. Out of 250 patients, 78% of the patients and 90% were delivered by normal vaginal delivery in control group and study group respectively. Out of 250 patients, 22% of the patients and 10% were delivered by caesarean delivery in control group and study group respectively.

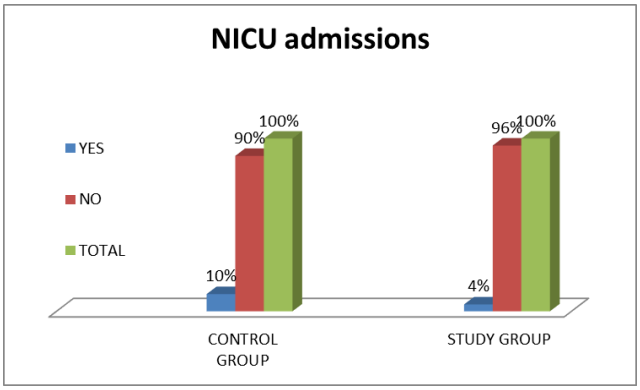

Figure 2: Distribution of the newborn babies according to NICU admission

In our study group, only 10% of the control group and 4% of study group of total babies born needed NICU admissions all of them were discharged healthy indicating better fetal outcomes.

In our study group majority of babies had a good APGAR score at birth and 5^{th} minute. 86% of the babies and 96% of the babies had APGAR of ≥ 7/1,9/5 in control group and

Table 2: Distribution of the patients according to the mode of delivery

Mode of delivery	Control group	Percentage	Study group	Percentage
Vaginal delivery	195	78%	225	90%
Cesarean delivery	55	22%	25	10%
Total	250	100%	250	100%

Table 3: Distribution of the new born babies according to APGAR

APGAR Score	Study group	Percentage	Control group	Percentage
>=7/1,9/5	240	96%	215	86%
<7/1,9/5	10	4%	35	14%
Total	250	100%	250	100%

Chi square value = 15.26, Dof = 1, P-value = 0.00009355 (Significant)

study group respectively. 4% of the babies in study group and 14% of the babies in control group had APGAR of < 7/1,9/5.

Table 3 shows the degree of pain. In the study group 50% patients had Grade I i.e., no pain after administering tramadol IM in first stage compared to the control group in which only 36.8% patients had no pain in first stage. In the study group, 10% patients had Grade II pain before administering tramadol IM and 4.8% had Grade II pain after tramadol IM administration. During first stage in the study group 7.2% and 38% had Grade III and Grade IV respectively. Whereas in the control group, 11.2% and 47.2% had grade III and IV pain in the first stage. This was found to be statistically significant. During second stage, 6% in the study group and 6.8% of control group had grade II pain. 10% and 43.2% of patients in study group had Grade III and IV pain, whereas 13.2% and 54.4% of patients in control group had Grade III and IV pain respectively, which was statistically significant.

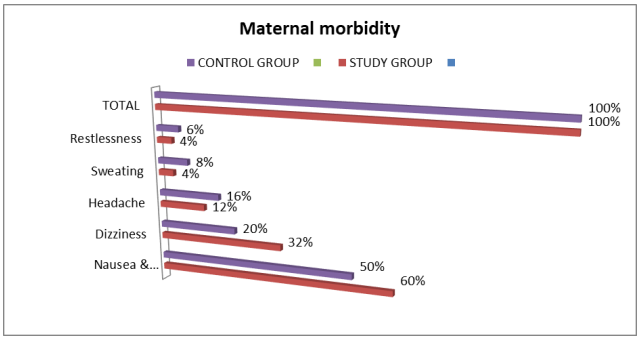

Figure 3: Maternal morbidity Chi square value = 13.3, Dof = 4,P-value = 0.009890 (Significant)

Research has established beyond a shadow of a doubt that tramadol works very well as an analgesic in labour and reduces the degree of pain during both the first and second stages. Nausea, vomiting, headache, dizziness, tingling in the legs, restlessness, perspiration, burning in the legs, and hypotension were the side effects.

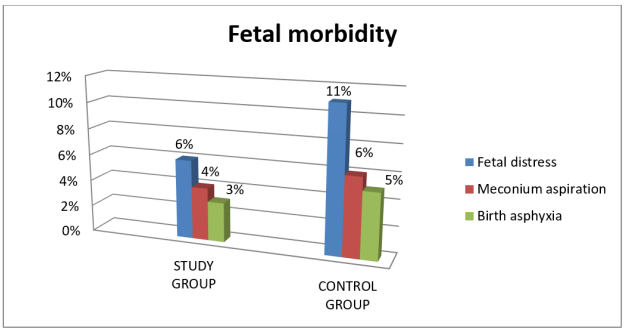

Figure 4: Fetal morbidity Chi square value = 0.2456,Dof = 2, P-value = 0.8844 (Not Significant)

Figure 2 shows foetal morbidity in both the groups. In this study, 6% of study group and 11% of control group showed Fetal distress. Meconium aspiration is seen in 4% of study group and 6% of control group.3% of study group and 5% of control group showed Birth Asphyxia.

5. Discussion

According to Sir James Young Simpson in 1848, "The misery and pain which women frequently experience when going through labour are beyond description and seem to be more than human nature would be able to bear under any other circumstance. Pain is a subjective sensory sensation. The scientific study of pain is a topic with unusual obstacles, which are eloquently outlined by H.R. Beecher. Hewer and Kell first introduced the pain score technique in 1948 for evaluating the effectiveness of the various types of analgesia, and it has since been widely applied.

The use of strong narcotics for post-operative pain management dates back a long time, and it once felt as though analgesia, emesis, respiratory depression, and addiction potential were mutually exclusive. Tramadol is an exception to this rule. The narcotic opioid tramadol was first made available to the public in 1971 in Germany. It has recently been made available in India. It is a weak opioid analgesic that only has agonist effects when it interacts

Table 4: Degree of pain relief

Degree of pain	Study group						Control group			
	Before giving drug	Percentage	I-stage	Percentage	II-stage	Percentage	I-stage	Percentage	II-stage	Percentage
Grade 1	0	0	124	50%	102	40.80%	92	36.80%	64	25.60%
Grade 2	25	10%	12	4.80%	15	6%	12	4.80%	17	6.80%
Grade 3	50	20%	18	7.20%	25	10%	28	11.20%	33	13.20%
Grade 4	175	70%	96	38.00%	108	43.20%	118	47.20%	136	54.40%
Total	250	100%	250	100%	250	100%	250	100%	250	250

Stage 1- Chi square value = 9.176, Dof = 3, P-value = 0.02704 (Significant), Stage 2- Chi square value = 13.14, Dof = 3,9, P-value = 0.004343 (Significant)

with mu, delta, and kappa opioid receptors. The effect of intramuscular tramadol on labour between the age groups of 18 and 35 years was examined in the current study. Both the study group and the control group considered primi, multi, and grandmulti. With the same inclusion and exclusion criteria, 250 patients were picked for the study group and 250 others for the control group.

As pain is a subjective experience, measuring how much it is relieved is challenging. In the current study, the amount and degree of pain reduction were determined by interviewing the patient. It was simpler to describe pain relief by RUPEE SCALE because the majority of our patients are uneducated.

Maternal mortality cases were absent from both the study and control groups.

In our study group, the majority of patients (64%) belong to the 18-24 yrs. age group, the youngest being 18 years and the oldest being 36 years. In the study by Thakur Ratna et al. the mean age in years is 22 years.[12] The mean maternal age was 22.43 in the tramadol group. The mean age and the range of ages were statistically compatible with present study.

Out of the total study group women, 58% were Primigravida and 42% were Multigravida. A study conducted by Shyamsundar B et al. maximum number of patients were primi and the next preponderance were multigravida.[13]

Out of 250 patients of study group, 90% of the patients were delivered by normal vaginal delivery, and 10% of the total patients delivered by caesarean section. Out of 250 patients of control group, 78% and 22% of the total patients delivered by normal vaginal delivery caesarean section respectively. In this study the caesarean section rate was statistically significantly lower when compared to the control group. In the study conducted Vanitha M et al. spontaneous vaginal delivery occurred in 82.5% of women in Tramadol group and 83.5% of women in control group. The percentage of caesarean section was 10% in Tramadol group and 10.5% in control group.[14]

In our study group, only 4% of the study group and 10% of control group of total babies born needed NICU admissions. Rest all of them were discharged healthy indicating better fetal outcomes. A Study conducted by Shyamsundar B et al.in the study group 8% babies had foetal distress as compared to 3% in the control group, 2 babies had meconium aspiration compared to 1 in the control group. This baby had to be resuscitated and shifted to NICU.[13]

In our study group majority of babies had a good APGAR score at birth and 5^{th} minute. In the Bajaj P et al., study, the APGAR score was 8-10 at 5 minutes in all the babies. The result of the referral study was comparable to the present study, which indicates that the drugs have no effect on the foetus.[15]

In the study group 50% patients had Grade I i.e., no pain after administering Intramuscular tramadol in first stage compared to the control group in which only 36.8% patients had no pain in first stage. In the study group, 10% patients had Grade II pain before administering the drug and 4.8% had Grade II pain after drug administration. During first stage in the study group 7.2% and 38% had Grade III and Grade IV respectively. Whereas in the control group, 11.2% and 47.2% had grade III and IV pain in the first stage. This was found to be statistically significant. During second stage, 6% in the study group and 6.8% of control group had grade II pain. 10% and 43.2% of patients in study group had Grade III and IV pain, whereas 13.2% and 54.4% of patients in control group had Grade III and IV pain respectively, which was statistically significant. This study is comparable to Thakur Ratna, Nagaria Tripti, Sudha patil, Meena Jyothi, Sarkar B. Mukhopadhyay et al. studies. Bajaj et al. conducted a randomized prospective study and concluded that Tramadol gives 38.92% mean pain relief.[12,15]

The duration of the analgesic effect after a single dose of Intramuscular Tramadol injection is about 6 hours. The duration of labour is shortened by Intramuscular Tramadol Injection, which is also safe and efficient.

There are no drug Interactions noted with Injection Tramadol and other drugs used in the Induction of labour.

6. Conclusion

This study shows that Intramuscular Tramadol Injection is a safe, effective and shortens the duration of labour period. It

is safe for both mother and baby that can be used for labour analgesia with little to no morbidity and no death. It gives the expecting woman all the pleasure of a typical delivery, without the misery of labour pains, or at least significantly lessens them.

Intramuscular first-stage labour pain can be well managed with tramadol hydrochloride, which also helps to shorten the time between the first and second stages. Moreover, the duration of the third stage of labour was unaffected by tramadol. Instrumental or caesarean section rates significantly decreased as a result of Injection Tramadol. There were no adverse effects on the mother or the foetus from Tramadol. Tramadol didn't lengthen hospital stays or increase maternal morbidity, making it a cost-effective medication.

7. Source of Funding

None.

8. Conflict of Interest

There is no conflict of interest between the authors.

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