

## Use of Intramuscular Tramadol Injection As A Labour Analgesic And Labour Accelerator.

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**Abstract:** Labour pain is among the most severe pain experienced by women. In developing nations, intramuscular opioids can be considered to overcome labour pain. The study is conducted to evaluate the efficacy of intramuscular Tramadol as a labour analgesic, labour accelerator and its effect on both mother and newborn. In this prospective study, 50 low risk primigravida patients who fulfilled the selection criteria of a full-term pregnancy with vertex presentation with good uterine contractions and already in active phase of labour were administered 50 mg Tramadol hydrochloride intramuscular injection and compared with 50 controls. The degree of pain relief in active stage of labour, injection delivery time, Apgar score of neonates and side effect of drugs were analysed. It was seen that after administration of Tramadol HCL IM, there was reduction of pain during vaginal delivery with minimal side effects like nausea & vomiting compared with control. IM Tramadol HCL appears to be effective as labour analgesic with minimal side effects. Hence, IM opioids can be considered as a suitable cost effective alternative in developing countries.

**Keywords:** Apgar score, Labour analgesia, Tramadol HCL, injection delivery time, intramuscular opioids.

### I. Introduction

Giving birth is a painful process. This applies to all social and ethnic groups and has probably been so since mankind walked up right<sup>1</sup>. Nulliparous women are more likely to experience severe pain than multiparous women<sup>2</sup>. Rickford and Regnolds suggest that it is not that women underestimate the pain but tend to overestimate their ability to cope with it<sup>3</sup>. Various ways either non-pharmacologic eg emotional sustain, psychoprophylactic preparation, yoga and hypnosis or pharmacologic such as epidural blockade or parenteral are used<sup>4</sup>. Labour can be both physically and psychologically stressful for a woman and the resulting detrimental effects on the fetus are well documented<sup>5</sup>. Adequate analgesia during labour is of benefit to the mother and has a positive influence during the course of labour and the state of newborn child, thus making obstetrical analgesia an essential part of modern obstetrics<sup>6</sup>. Choice among a variety of methods and individualization of pain relief is desirable<sup>7</sup>. An ideal analgesic technique used should be cheap, easy to administer, produce good and reliable relief from pain but not impair consciousness. It should not be toxic to mother and fetus. The technique must have no tocolytic action or delay labour<sup>8</sup>. Use of epidural analgesia is limited in India due to lack of awareness, trained staff and monitoring facilities and injectable opioids such as meperidine<sup>9</sup>. Tramadol, a weak opioid agent inhibits noradrenergic and serotonergic neurotransmission having analogous analgesic efficacy to meperidine and less sedative effect on the mother and less neonatal respiratory depression<sup>10</sup>.

### II. Materials And Methods

The study was a prospective, randomised clinical trial carried out at the labour room in 100 primi gravida women. All primigravida women presenting with full term pregnancy with vertex presentation, singleton fetus and in active phase of labour were included in inclusion criteria. 4 cm of cervical dilatation, 50% or more effacement of cervix with good uterine contractions were criteria for active labour. Parturient with history of medical disorders and obstetrical complications and history of alcohol abuse were excluded. Once the patient is in active phase of labour i.e. 4 cm dilatation, 50% or more effacement with good uterine contractions, vital signs recorded and primary investigations done and pain score was noted before administering the drug. ARM (Artificial Rupture of Membrane) done and injection Tramadol 50 mg IM (upto 60 kg) or less and 75 mg (61-75 kg) was given. Pulse rate, respiratory rate, BP, FHR were recorded. Patient was advised to inform as soon as pain began to decrease in intensity or even if there was no pain relief at all. Partogram done to assess the progress of labour, maternal and fetal conditions. Onset of action of drug, side effects, FHR and progress of labour were monitored.

Assessment of analgesia was done hourly by scoring system and also injection delivery interval was accurately recorded. The injection delivery interval was arbitrary fixed at 3 hours. Patient level of consciousness, alertness, psychological disturbances were judged.

The duration of labour, degree of pain relief and the mode of delivery in each patient were noted and recorded. Apgar score at 1 and 5 minutes interval after delivery of neonate were recorded.

The degree of pain relief was expressed as percent of the whole rupee. (Rupees scale)

The degree of pain was graded as shown below (as per Rupees Scale):

**Grade – I:** No pain.

**Grade – II:** Mild pain but comfortable : 25%.

**Grade – III: Moderate pain with discomfort : 50%.**

**Grade – IV:** Maximum pain/severe pain:  $\geq 75\%$ .

### **III. Result**

In this study, 50 patients of different age group were studied to evaluate the efficacy and safety of Tramadol hydrochloride in providing pain relief during labour and its side effects on mother and the new-born. Mean age of women in the study with Tramadol was 21 years with standard deviation of 2.14 years. Mean age of women in the study without Tramadol was 23 years with standard deviation of 4 years. Before administration of Tramadol, maximum patients 35 i.e.70% had grade IV type of pain. After administration of drug, maximum patients i.e. 50 (100%) had grade II type of pain. The mean degree of pain before administration of drug is 3.81. After administration of drug, the mean degree of pain was 2. The P value is 0.0001. Without administration of drug, maximum patients i.e. 30 (60%) had grade III type of pain and 20 (40%) had grade IV type of pain. The mean degree of pain was 3.40.

Maximum patients i.e. 22 (44%) had injection delivery time between 1 & 2 hours and 11 patients i.e. 22% of women had injection delivery time less than 1 hour. 10 (20%) of women had injection delivery time between 2 and 3 and 7 (14%) of women had injection delivery time of more than 3 hours. The P value is 0.0001. There was no significant difference in the Mean Apgar score of neonates with or without Tramadol.

### **IV. Discussion**

Tramadol is an effective analgesic that can be used for the treatment of intense acute and chronic pain such as post operative and obstetric pain. Tramadol hydrochloride, a narcotic drug introduced in Germany in 1971 is readily available throughout the world. In obstetric analgesia, 100 mg Tramadol hydrochloride administered intramuscularly has an analgesic effect equivalent to that of 100 mg pethidine or 10 mg morphine administered intramuscularly<sup>11</sup>. Tramadol is a weak opioid analgesic which interacts with with  $\mu, \delta$  &  $\kappa$  opioid receptors, where it exhibits purely agonist effects<sup>12</sup>.

In the present study, the effect of intramuscular Tramadol when given to 50 primigravida women in active stage of labour of age 18-35 years were evaluated. There is no doubt that labour pain is one of the most intense pains experienced but the perception of pain varies strikingly between individuals. The degree of pain relief was assessed by asking the patient the extent and degree of pain relief. Analgesia described by Hever and Kell in 1948<sup>13</sup>.

1. Grade – I: No pain.
2. Grade – II: Slight pain but comfortable.
3. Grade – III: Moderate pain with discomfort.
4. Grade – IV: Maximum pain/severe pain.

Out of 50 patients in the present study before administering the drug, 30% had grade-III and 70% had grade-IV, i.e. maximum pain. After administration of 50 mg Tramadol intramuscularly, there was reduction of pain from grade-III and IV to grade-II in all the 50 patients. Without Tramadol, the other 50 women had grade-III or grade-IV pain throughout the delivery. Pain relief was comparably good and all the patients 50(100%) in our study group had pain relief. This has proved beyond doubt that Tramadol has very good efficacy as an analgesia in labour and it has decreased the intensity of pain. There was no statistical difference in the injection delivery interval of patients with Tramadol and without Tramadol. There was no statistical difference in the neonatal outcome in both groups. Minimum side effects of Tramadol was seen in our patients with no significant change in maternal vital parameters, thus proving safety of Tramadol as an obstetric analgesic. Programming of labour with Tramadol is a simple, easy and effective method of painless and safe delivery. The analgesia produced is quite effective and overall duration of labour is significantly reduced. Blood loss in third stage is also significantly reduced. Maternal side effects are minor without any significant fetal or neonatal respiratory depression.

### **V. Summary And Conclusion**

It may be safely concluded that Tramadol is a safe and satisfactory drug for relief of labour pain and as labour accelerator. The degree of pain and duration of labour is significantly reduced in patients who are administered Tramadol hydrochloride.

**VI. Table and Figures**

**Table 1: Degree of pain relief (With Tramadol)**

Degree of pain	Before admn of drug	After admn of drug
Grade I	0	0
Grade II	0	50 (100%)
Grade III	15 (30%)	0
Grade IV	35 (70%)	0
Total	50	50
Mean degree of pain	3.70	2.00
SD of pain	0.46	-

**Table 2: Degree of pain relief (Without Tramadol)**

Degree of pain	Without Tramadol
Grade I	0
Grade II	0
Grade III	30 (60%)
Grade IV	20 (40%)
Total	50
Mean degree of pain	3.40
SD of pain	0.49

**Table 3: Injection Delivery Time ( With Tramadol)**

Duration of labour from active stage (in hrs)	No. of women	Percentage
< 1	11	22
>1 or equal but <2	22	44
>2 or equal or <3	10	20
>3	7	14
Total	50	100

**Table 4: Injection Delivery Time ( Without Tramadol)**

Duration of labour from active stage (in hrs)	No. of women	Percentage
< 1	-	-
>1 or equal but <2	4	8
>2 or equal or <3	11	22
>3	35	70
Total	50	100

**Table 5: Mean Apgar score of neonates (With Tramadol)**

Time (in minutes)	Mean apgar score	SD of apgar
01	7.42	0.70
05	8.52	0.58

The mean APGAR score at 1 minute is 7.42.

The Mean APGAR score at 5 minutes is 8.52.

**Table 6: Mean APGAR score of neonates (Without Tramadol)**

Time (in minutes)	Mean apgar score	SD of apgar score
01	7.40	0.64
05	8.44	0.64

The mean APGAR score at 1 min is 7.40.

The mean APGAR score at 5 min is 8.44.

**Table 7: Injection delivery interval (With Tramadol)**

Mean injection delivery interval	1.74 hours
Standard deviation of IDI	0.90 hours

The mean IDI is 1.74 hours.

**Table 8: Injection delivery interval (Without Tramadol)**

Mean duration of labour	2.95 hours
Standard deviation of duration of labour	0.73 hours

**Table 9:** Summary of statistical Analysis of the study.

Variables	Mean Value		Standard Deviation	
	With Tramadol	Without Tramadol	With Tramadol	Without Tramadol
Age in years	21.1	23.14	2.14	4.04
Injection Delivery Interval (hours)	1.74 P value =0.0001	2.95	0.90	0.73
Pain score	P value=0.0001			
Before admission of drug	3.70		0.46	
After admission of drug	2.00	3.4	0.00	0.49
Apgar score				
At one minute	7.42	7.40	0.70	0.64
At five minute	8.52	8.44	0.58	0.64
Birth weight (kg)	2.83	2.75	0.34	0.39

The P value for pain score as well as injection delivery time with Tramadol is significant. Use of intramuscular tramadol injection as a labour analgesic and labour accelerator.

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