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## Original Research Article

# A study of efficacy of intramuscular injection tramadol as labour analgesic and labour accelerator in 400 primigravida patients in latent phase of first stage of labour

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### ABSTRACT

**Background:** Labour pain is among the most severe pain experienced by women. Most women like to experience labour birth with active involvement and as naturally as possible. Hence, the need for analgesia to overcome labour pains is highly requested by women today. In developing nations where availability of facilities is the main limiting factor, intra muscular opioids can be used. The aim was to know the effect of Tramadol in labour analgesia and reduction in the duration of labour and to know the maternal and neonatal outcome after administration of Tramadol

**Methods:** This study was conducted in tertiary teaching care hospital in 400 low risk primigravidae who fulfilled selection criteria with full-term pregnancy with vertex presentation in late latent phase of labour were selected and given 100 mg tramadol hydrochloride intramuscularly.

**Results:** The degree of pain relief in 1<sup>st</sup> and 2<sup>nd</sup> stage of labour, duration of labour, Apgar score of neonates and side effect of drugs were studied. In this study 23.5% of patients had grade II pain, 38.5% of patients had grade III pain and 38% of patients had no pain relief after Tramadol administration. Before drug, the mean pain score is 3.86 in stage I. After drug administration the mean pain score is 3.14 in stage I and 3.81 in stage II. The duration of first and second stage of labour also shortened.

**Conclusions:** In low risk Primigravidae, IM Tramadol hydrochloride appears to be effective without side effects. Hence, in developing nations, where availability of facilities is the main limiting factor, IM opioids can be considered as suitable alternatives.

**Keywords:** Numeric pain intensity scale, Latent phase of labour, Primigravida, Tramadol

### INTRODUCTION

The birth of the first baby, the culmination of the first pregnancy signifies a momentous occasion in the life of every woman. The aim of modern management of labour should be to ensure optimum condition for the mother and the fetus during and after delivery and to render emotional support and satisfaction. It involves general care and support of the mother, monitoring the condition of the foetus and progress of labour; so as to anticipate, recognize problem that endangers the life of both mother

and baby. Labour pain is due to physiological, psychological, excitatory as well as inhibitory complex interactions. Labour pain exceeds the women's ante partum expectation. It may affect cardiovascular, respiratory, urinary, gastro intestinal, neuro endocrine functions due to supra segmental and segmental reflexes. It also decreases 25% of utero placental blood flow and causes altered fetal homeostasis. Painless short labour is usually preferred by every mother and has been a primary concern of an obstetrician and it has a positive influence on the course of labour. Thus, obstetrical analgesia

becomes an essential part of modern obstetrics. Various methods of obstetrical analgesia are available.

This has been discussed in various literature as follows, Nulliparous women are more likely to experience severe pain than multiparous women.<sup>1,2</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, psycho-prophylactic 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 new-born 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> Epidural analgesia has been popularly used for pain relief in western countries for nearly three decades. In India its use is limited due to lack of trained staff, awareness and monitoring facilities. Inhalational Entonox contains 50% Nitrous Oxide+50%Oxygen also used as labour analgesia. It has many advantages like rapid reversibility, patient controlled system, less possibility of over dosage and higher oxygen delivery to fetus. Its disadvantage is the need for anaesthesiologists. So, it could not be used in smaller hospitals. Because of convenience of administration, faster absorption as compared to the oral route IM Tramadol hydrochloride was used for the study. Tramadol is a weak opioid agent inhibits noradrenergic and serotonergic neurotransmission and has analgesic activity. Tramadol allays sympathetic anxiety. It also inhibits type III Muscarinic Receptors. M-3 Receptor antagonism causes inhibition of gastric gland secretion and relaxation of smooth muscle. Thus, it reduces the duration of labour also. Analgesic effect of parenteral tramadol in labour found to have no adverse effect on the course of labour or on the new-born. It did not exert inhibitory effect upon respiratory centre. A study conducted to know the pharmacodynamic and pharmacokinetic properties and therapeutic potential of Tramadol found that it is well tolerated in short term use with dizziness, nausea, vomiting, sedation, dry mouth and sweating being the principal adverse effects. Respiratory depression was observed in few patients when tramadol infusion was given for pain relief in labour, but it did not cause respiratory depression in neonates.<sup>8</sup> Analgesic potency and tolerability of IM tramadol was compared with standard obstetric analgesic pethidine. Tramadol was proved to be safe for both mother and child and caused effective pain relief.<sup>9</sup> In another study, the analgesic efficacy and safety of tramadol was compared with

Pethidine. It concluded that 100mg IM tramadol is as effective as 75mg pethidine for pain relief in labour and has a superior safety profile both on mother and foetus.<sup>10</sup>

The pioneers in obstetric analgesia have proved that it can be used with adequate care and skill. Ideal analgesia is one which is safe, provide good analgesia, does not cause maternal and foetal depression, does not affect the progress of labour, does not have unpleasant side effects and has high technical success rate.<sup>2</sup> In the present study the merits, demerits and outcome of IM Tramadol hydrochloride as labour analgesic and labour accelerator and the effect of the drug in both the mother and baby is evaluated.

## METHODS

Drug used was IM Tramadol hydrochloride with dose of 1 ampoule contains 2 ml, in which 1ml is equal to 50 mg. Study design was comparative prospective interventional study.

A total of 400 Primigravida who were admitted to the labour ward of GOVT RSRM HOSPITAL during the period October 2012 to November 2013, in late latent phase (i.e.,) with cervical dilation of 2- 3cm were enrolled in this study after getting informed consent. They had fulfilled the inclusion criteria and exclusion criteria with informed consent.

Also, if the pregnancy has medical, surgical or obstetric complication such as ante partum haemorrhage, preeclampsia, malpresentations and cephalopelvic disproportion where also excluded. Similarly, in mothers in whom labour was induced, cervical dilatation greater than 3cms was present, Ruptured membranes were present and patients who have not given consent for the study were excluded from present study

The selected patients were randomly divided into two groups I and II. Group I was given IM Tramadol hydrochloride 100mg in late latent phase of labour. Group II was a control group, without giving Tramadol. Progress of labour was monitored by Partograph in both groups. Effectiveness of the drug was assessed by noting Pain score before and after drug administration. Numeric Pain Intensity Scale is used for assessing labour pain. Observations were made at 0, 30, 60, 90 and 120 minutes after the medication. Also, the duration of the first stage, total duration of labour, mode of delivery, maternal side effects, Fetal outcome and duration of hospital stay were noted for analysis

Initial dose of drug was given at 2- 3cm dilatation of cervix. The patients were reviewed after 2 hours and dose repeated for the patient who had severe pain and withheld in patients who had already entered into the second stage. This study was approved by institutional human ethics committee.

**Inclusion criteria**

- Primigravida who were between 18-35years of age completed 37 weeks of gestation, having 2-3cm of cervical dilatation with intact membrane and adequate pelvis for vaginal delivery.
- Further only if there was Singleton foetus with Vertex presentation who went in for spontaneous labour.

**Exclusion criteria**

- Multigravida patients who are allergic to Tramadol hydrochloride after subcutaneous test dose.

**RESULTS**

In present study population majority of the primigravida were found to be between 21-25 years of age in both the groups. The chi square statistical test infers that age distribution was similar in the two groups. The difference between the age groups of groups I and II were not statistically significant. Hence the two groups were comparable age wise. Similarly, majority of the patients were found to be between 39.1-40 weeks gestational age. The gestational age distribution was similar in the two groups. No statistical difference in the gestational age was present between two groups.

Coming to degree of pain in stage I before drug administration in both groups. In stage I, 87% of the patients in group I and 85.5% of the patients in group II had severe pain whereas 13% of patients in group I and 14.5% of the patients in group II had moderate pain. Hence pain score before drug administration is comparable in both groups with no statistical difference (p value-0.707) between two groups. Next, authors analysed degree of pain after drug administration (Table 1).

**Table 1: Degree of pain.**

Degree of pain	In study group	
	Before drug	After drug
No pain	0	0
Mild	0	47
Moderate	26	77
Severe	174	76

In group I patients after drug administration the pain score is significantly decreased (p value-<0.0001). In group I, 23.5% of the patients had moderate pain relief and 38.5% of the patients had mild pain relief and 38% of patients had no pain relief.

Further authors analysed degree of pain in stage II in study and control group. In group I 85.5% of the patients had severe pain, 14.5% of the patients had moderate pain. In group II all patients had severe pain. The pain in stage

II in group I is less than group II which is also statistically significant (p value-<0.001).

Further pain relief was analysed using mean pain score in labour in both groups (Table 2).

**Table 2: Mean pain score.**

Mean pain score	Study group	Control group	P value
Stage I before drug	3.86	3.85	0.708
Stage I after drug	3.14	3.85	0.001
Stage II	3.85	4	0.001

After drug administration, the mean pain score is decreased in stage I and stage II labour in group I patients than group II patients which are statistically significant. Authors also analysed the duration of all three stages of labour in both groups. Duration of I<sup>st</sup> and II<sup>nd</sup> stages of labour is decreased in study group than control group which was statistically significant whereas duration of third stage of labour was not statistically significant (Table 3).

**Table 3: Duration of labour.**

Duration of labour (in min)	Study group	Control group	P value
Stage I	265.93	284.98	0.003
Stage II	24.89	28.21	0.012
Stage III	8.83	9.43	0.089

The average total duration of labour in the group I is 290.21±65.43minutes. The average total duration of labour in the group II is 320.55±68.31minutes. The total duration of labour is less in group I patients than group II patients. Authors analysed the various modes of delivery in the two groups. Majority of patients in group I (82.5%) had normal vaginal delivery, similarly 83.5% of patients had normal vaginal delivery in groups II respectively. The incidence of operative delivery is also equal in both groups. There was no statistical difference between groups. Similarly, there was no difference in birth weight between groups. The mean birth weight was 2.82±0.44 and 2.80±0.39 kilograms in group I and II respectively and was statistically not significant. It was similar in the two groups.

Next, authors move on to immediate neonatal outcome in groups I and groups II. In the majority of babies in both the groups the Apgar score was 7/10 at 1 min and 8/10 at 5 minutes. The t test infers that there was no significant difference in the Apgar scores in the two groups. Both the groups were similar and no statistically significant difference was noted in the two groups. Moving on to maternal side effects and complications by group (Table 4). Nausea, vomiting, drowsiness, respiratory distress are present in both groups. Maternal side effects are similar in both groups. There was no difference between the two groups in terms of the maternal side effects. Similarly,

maternal complications like vaginal tear are similar in both groups. There was no difference between the two groups in terms of the maternal complications. Only 25% of patient needed additional dose. Duration of hospital stay was also analysed in present study group. Majority of the patients in both groups required 2-4 days of hospital stay. The chi square statistical test infers that duration distribution was similar in the two groups. There was no difference between the two groups in terms of duration of hospital stay.

**Table 4: Maternal adverse events.**

Adverse events	Group I		Group II	
	No.	%	No.	%
Nausea	15	7.5	21	11
Vomiting	15	7.5	21	11
Drowsiness	2	1	1	0.5
Respiratory distress	2	1	1	0.5

## DISCUSSION

An ideal method for pain relief in labour should combine safety for the mother and the foetus without any side effects and should be convenient for the patient and the attendant physician. The present study was designed to evaluate the efficacy of IM Tramadol Hydrochloride in the late latent phase of first stage of labour.

The study randomized two groups of 200 pregnant women each fulfilling the inclusion criteria. Group I included patients treated with IM Tramadol in latent phase of labour whereas group II included patients who didn't receive IM Tramadol in latent phase of labour. The two groups were standardized and compared regarding the degree of pain relief, duration of labour, mode of delivery, fetal outcome, maternal morbidity and hospital stay. The adverse effects of the drug on the mother and newborn were also noted.

The present study had an age range of 18-35 years. 53% and 50.5% of women were in age group of 21-25 years in groups I and II respectively. The difference in the age group among the two groups was not statistically significant with a p value-0.691. There was an identical age distribution in both the groups. This was to remove any effect of age on degree of pain relief and duration of labour. In the study by Thakur Ratna et al the mean age in years was 22 years. The mean age and the range of ages were statistically compatible with the present study. Thus, Age distribution was similar to the present study.<sup>11</sup>

In the present study the gestational age, ranged between 37-40 weeks and above. 45% and 37.5% of women were in the gestational age of 39.1-40 weeks in the groups I and II respectively. The variation in the gestational age among the two groups was not statistically significant (p-value=0.075). This was to remove any difference in the degree of pain relief and duration of labour due to difference in the gestational age. The mean period of

gestational age was 39 weeks in the study by Nagaria Tripti et al. and Sudha Patil et al. The mean gestational age and the range of gestational age were comparable with the present study. Also similar to the study by Lie et al, all patients in present study group were Primigravida.<sup>12-14</sup>

The measurement of degree of pain relief by visual analogue scale, cervical effacement and dilatation, position of the cervix and the station of the presenting part were observed, and findings were recorded on a partogram. There was no significant difference in the effacement of the cervix, dilatation of the cervix, station of the presenting part or the position of the cervix in the two groups. Any bias relating to the above on progress of labour has been removed.

### *Degree of pain relief*

Onset of pain relief in the present study was 15-20 minutes. Onset of pain relief in the study by Nagaria Tripti et al. and study by Sudha Patil et al. was 15-20 minutes. The same was present in this study.<sup>12,13</sup> In this study 23.5% of patients had moderate pain relief, 38.5% of patients had mild pain relief and 38% of patients had no pain relief after Tramadol administration. Before drug, the mean pain score is 3.86 in stage I. After drug administration the mean pain score is 3.14 in stage I and 3.81 in stage II. The pain score is increased from stage I to stage II in group I. 14.5% of patients had moderate pain, 85% of patients had severe pain. Only 85% of the study group experienced severe pain in stage II. But 100% of patients in group II experienced severe pain. This denotes statistical significance between the two groups. This study is comparable to Thakur Ratna, Nagaria Tripti, Sudha patil, Meena Jyothi, Sarkar B. Mukhopadhyay et al studies. Bajaj et al conducted a randomised prospective study and concluded that Tramadol gives 38.92% mean pain relief.<sup>11-17</sup>

In one another randomized control trial done they compared IM Opioids like Meperidine and Tramadol's Analgesic efficacy with Epidural Analgesia and concluded that Tramadol group patients had 65% pain relief. Li E and Weng studied the efficacy of Tramadol 100mg in latent phase of labour and 67% of patients had pain relief in first stage of labour.<sup>14</sup> O Kuti et al compared Tramadol with Pentazocine in labour and concluded that mild pain relief present in 66% of patients, moderate pain relief present in 30.9% of patients in Tramadol group. Singh et al compared 100mg IM Tramadol with Pentazocine and concluded that 80% of Tramadol group had moderate pain relief.<sup>18,19</sup>

The duration of latent phase of first stage of labour was calculated from the onset of regular uterine contractions to the time of cervical dilatation of 3-4cms. In the present study the mean duration of first stage of labour in group I is 265.93±64.066 min. The mean duration of first stage of labour in group II is 284.98±56.28 min. It was found that

there was a statistically significant shortening in the duration of first stage of labour in the Tramadol group when compared to the control group (p value – 0.003). The duration of second stage of labour also significantly reduced in group I compared to group II. No significant change was observed in the duration of Third stage of labour in the control and study group. This concluded that Tramadol will not prolong the Third stage of labour and will not produce third stage complications.

The average total duration of labour in group I is 290.21±65.43 minutes. The average total duration of labour in group II is 320.55±68.31 minutes. The total duration of labour is significantly less in group I. Similar to this study conducted by Thakur Ratna et al, Nagaria Tripti et al, Sudha Patil et al, Mukhopadhyay AK, Khooshideh M et al concluded that IM Tramadol reduces the duration of labour.<sup>11,12,13,16,20</sup> It may be hence summarised that Tramadol is effective in shortening the duration of labour.

Coming to mode of delivery in the present study spontaneous vaginal delivery occurred in 82.5% of women in Tramadol group and 83.5% of women in control group. Only 7.5% in Group I and 5.5% in Group II had instrumental vaginal delivery in the form of forceps application. The indications were second stage foetal distress, 3.5% in Group I, 2.5% in Group II and Maternal exhaustion 4.5% in Group I and 3% in Group II. The percentage of caesarean section was 10% in Group I and 10.5% in Group II. No significant difference was noted in the mode of delivery in both groups.

Authors also analyzed the neonatal outcome, to start with birth weight, the mean birth weight was 2.82±0.44 and 2.80±0.39 kg in Group I and II respectively. It was not statistically significant, p value- 0.649. This is to remove any influence of the mean birth weight on the rate of cervical dilatation, cephalo pelvic disproportion and dystocia which would indirectly influence the duration of first stage of labour and the total duration of labour.

Authors also analyzed APGAR score: The mean APGAR scores at 5minutes are 8.1±0.92 and 8.2±0.82 in Groups I and II respectively. The difference among the two groups was not statistically significant (p value = 0.303). 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.

Maternal morbidity was also analyzed. The various side-effects observed were Nausea, Vomiting and Drowsiness. All these maternal side-effects are similar in both groups. It concluded that Tramadol will not produce any adverse effects. Of the maternal complications, vaginal tear was noted in 29 and 28 patients in group I and II. No difference was noted between the two groups in terms of maternal complications. Coming to number of doses required 75% of the patients in the study group required

only a single dose and 25% of the patients required a second dose. No study observed the number of doses required and hence no comparison between referral studies was attempted.

Authors also analyzed the duration of hospital stay where majority of the patients in both groups required 2-4 days of hospital stay. The range difference between the duration of hospital stay in groups I and II were statistically not significant. There was no difference between the two groups in terms of duration of hospital stay. This concludes that Tramadol does not have any influence in duration of hospital stay.

## CONCLUSION

Intramuscular Tramadol Hydrochloride is effective in pain relief in first stage of labour and also it shortens the duration of first and second stage of labour. Also, Tramadol didn't affect the duration of third stage of labour. Tramadol caused no major increase in instrumental or caesarean section rates. Tramadol had no significant maternal or fetal side effect. It was found to be safe for both mother and baby. Tramadol didn't increase maternal morbidity and duration of hospital stay; hence the drug is cost effective.

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