

A Study of Efficacy of Intramuscular Injection Tramadol as Labour Accelerator in Primigravida

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ABSTRACT

BACKGROUND

Pain during labour is the most severe pain experienced by women in labour. The need for labour analgesia to overcome the labour pain is highly requested by women today. Intramuscular opioids can be considered in developing nations where availability of facilities is the main limiting factor. We wanted to evaluate the efficacy of intramuscular tramadol hydrochloride as a labour analgesic and labour accelerator by calculating pain relief scores in labour, the duration of labour and the effect of the drug on both mother and new born.

METHODS

The study was conducted in MVJ Medical College and Research Hospital, Bangalore. The selection criteria for primigravida was full-term pregnancy with good uterine contractions with vertex presentation and in active phase of labour. 50 selected primigravida were given intramuscular 50 mg tramadol hydrochloride and were compared with 50 cases without tramadol. After administration of tramadol in active stage of labour, degree of pain relief, injection delivery time, Apgar score of neonates and side effect of the drug were studied.

RESULTS

Before administration of the drug to 50 selected primigravida, there were no patients who had grade I or grade II pain. 30% had grade III pain and 70% had grade IV pain. There was reduction in pain from grade IV and grade III after administration of tramadol hydrochloride IM and all patients continued with grade II pain and delivered vaginally. Minimal side effects like nausea and vomiting were observed only in 4 women but in the other group i.e., without tramadol administration, there was no reduction of pain.

CONCLUSIONS

Tramadol hydrochloride administration IM appears to be effective in low risk primigravida with minimal side effects. Hence, IM opioids can be considered as suitable alternatives in developing nations, where availability of facilities is the main limiting factor.

KEYWORDS

Labour Analgesia, Tramadol Hydrochloride, Intramuscular, Intramuscular Opioids

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BACKGROUND

Parturition is a painful process. This has been so since mankind walked upright, and this applies to all ethnic and social groups.¹ Labour and delivery cause pain in most patients. Nulliparous women are more likely to experience severe pain than multiparous women.² 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 is to ensure optimum condition for the mother and the fetus during and after delivery and also to render emotional support and satisfaction. It comprises of general care and support of the mother, monitoring the condition of the fetus 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. Rickford and Regnolds suggest that it is not that women underestimate the pain, but they tend to overestimate their ability to cope with it.³

Labour can be both physically and psychologically stressful for a woman and the resulting detrimental effects on the fetus are well documented.⁴ During labour, it is beneficial to provide adequate analgesia to the mother which will have a positive influence on the state of neonate and the course of labour. Thus, in modern obstetrics labour analgesia is essential.⁵ 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. Various methods of obstetrical analgesia are available. The experience of labour pain is a highly individual reflection of variable stimuli that are uniquely received and interpreted by each woman individually. These stimuli are modified by emotional, motivational, cognitive, social and cultural circumstances. Choice among a variety of methods and individualization of pain relief is desirable.⁶

The need for labor analgesia to overcome labour pain is highly requested by women today. Various ways either non-pharmacologic or pharmacologic can be used. Non-pharmacologic ways like emotional sustain, psychoprophylactic preparation, yoga and hypnosis are used to overcome labour pain. Pharmacologic ways such as epidural blockade or parenteral are used.⁷ An ideal technique used for labour analgesia should produce good and reliable relief from pain, should be cheap, easy to administer, but it should not impair consciousness or cooperation. It should not be toxic to the mother and fetus and should not produce cardiorespiratory depression in the fetus. The technique should not have tocolytic action and should not delay labour. In western countries, epidural analgesia has been popularly used for nearly three decades for pain relief during labour. In India, meperidine and tramadol injectable opioids are reasonably used. Due to lack of awareness, trained staff and monitoring facilities, use of epidural analgesia is limited in India.⁸

Tramadol is a weak opioid agent which inhibits noradrenergic and serotonergic neurotransmission, having

analogous analgesic efficacy to meperidine and less sedative effect on the mother and less neonatal respiratory depression. 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.

In the present study, the efficacy of IM Tramadol hydrochloride as labour analgesia and labour accelerator when administered to primigravida in active phase of labour and the effect of the drug in both the mother and baby was evaluated.

METHODS

The study was prospective randomized clinical trial carried out in 100 primigravida who were admitted at term to MVJ Medical College and Research Hospital, Hoskote, Bangalore from November 2017 to October 2019. The present study included 100 primigravidae (50 with Tramadol and 50 without Tramadol) in active stage of labour by selecting them according to inclusion and exclusion criteria where tramadol hydrochloride 50 mg intramuscularly was administered during active phase of labour. The efficacy of tramadol hydrochloride was assessed based upon the degree of pain relief scores, duration of labour (injection delivery time), effect of drug on mother and newborn, Apgar score at 1 minute and 5 minutes.

The selection criteria for primigravida was full term pregnancy with singleton live fetus with good uterine contractions with vertex presentation and in active phase of labour. Exclusion criteria was primigravida with history of medical disorders and obstetrical complications and history of alcohol abuse. The criteria for active labour was cervical dilatation of 4 cm, effacement of the cervix 50% or more and with good uterine contractions. Primary investigations were done, and the vitals were recorded once the patient was in active phase of labour. Before administering the drug, pain score was noted. ARM was done. Then, injection tramadol 50 mg IM was given to primigravida. Pulse rate, respiratory rate, blood pressure, FHR were recorded. As soon as pain begins to decrease in intensity or even if there was no pain relief at all, the patient was instructed to inform. To assess the progress of labour, maternal and fetal condition Partogram was plotted. Onset of action of the drug, side effects, FHR and progress of labour were monitored.

Hourly assessment of labour analgesia was done by scoring system, and also injection delivery interval was accurately recorded. The duration of labour, degree of pain relief, and the mode of delivery in each patient was noted and recorded. Patient level of consciousness, alertness, psychological disturbances was observed. After delivery of the neonate, Apgar score at 1- and 5-minutes interval was recorded. The intensity of pain relief was expressed as percent of the whole rupee. The intensity of pain was graded as shown below (as per rupees scale): No pain -- 0 - 25%:

Grade-I; Mild pain but comfortable -- 25 - 50%: Grade-II; Moderate pain with discomfort -- 50 -75%: Grade-III; Maximum pain or severe pain -- ≥75%: Grade-IV

RESULTS

In this study, 50 patients of different age group were studied to evaluate the efficacy of tramadol hydrochloride in providing pain relief during labour and its labour accelerating property along with side effects on mother and the newborn. Mean age of women in the study group with Tramadol was 21 years with standard deviation of 2.14 years. Mean age of the women in the study group without Tramadol was 23 years with standard deviation of 4 years.

Degree of Pain	Before Administration of Drug n (%)	After Administration of Drug n (%)
Grade I	0 (0%)	0 (0%)
Grade II	0 (0%)	50 (100%)
Grade III	15 (30%)	0 (0%)
Grade IV	35 (70%)	0 (0%)
Total	50 (100%)	50 (100%)
Mean	3.70	2.00
Std. Deviation	0.4629	-

Table 1. Degree of Pain Relief in Study Group with Tramadol

Degree of Pain	Without Tramadol n (%)
Grade I	0 (0%)
Grade II	0 (0%)
Grade III	30 (60%)
Grade IV	20 (40%)
Total	50 (100%)
Mean	3.40
Std. Deviation	0.4949

Table 2. Degree of Pain Relief in Study Group without Tramadol

Injection Delivery Time (in mins)	With Tramadol	Without Tramadol	Total
<60	13 26.0%	0 .0%	13 13.0%
61-120	20 40.0%	4 8.0%	24 24.0%
121-180	10 20.0%	11 22.0%	21 21.0%
>180	7 14.0%	35 70.0%	42 42.0%
Total	50 100.0%	50 100.0%	100 100.0%

Table 3. Injection Delivery Time between the Study Groups (in mins)

p value = 0.000 (Significant)

Before administration of tramadol, maximum patients i.e. 35 (70%) had grade IV type of pain. After administration of drug maximum patients i.e. 50 (100%) are had grade II type of pain. The mean degree of pain before administration of drug was 3.70 and after administration of drug the mean degree of pain was 2.00. The p value is 0.0001 (Significant). Without administration of drug, maximum patients i.e. 30 (60%) are 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. 20 (40%) had injection delivery time between 61 to 120 minutes and 13 patients i.e. 26% of women had injection delivery time less than 60 minutes. 10 (20%) of women had injection delivery time between 121 to 180 minutes and 7 (14%) of women had injection delivery time than 180 minutes. The p value is 0.000 (Significant). The

mean injection delivery time with Tramadol was 107.46 minutes. The mean injection delivery time without Tramadol was 177.00 minutes. The mean APGAR Score with Tramadol at 1 minute was 7.42. The mean APGAR Score with Tramadol at 5 minutes was 8.52. The mean APGAR Score without Tramadol at 1 minute was 7.40. The mean APGAR Score without Tramadol at 5 minutes was 8.44. There was no significant difference in the mean APGAR Score of neonates with or without Tramadol.

	N	Minimum	Maximum	Mean	S.D.
Apgar Score at 1 min.	50	6	8	7.42	0.702
Apgar Score at 5 min.	50	7	9	8.52	0.580

Table 4. Mean Apgar Score of Neonates in the Study Group with Tramadol

	N	Minimum	Maximum	Mean	S.D.
Apgar Score in 1 min.	50	6	8	7.40	0.639
Apgar Score in 5 min.	50	7	9	8.44	0.644

Table 5. Mean Apgar Score of Neonates in the Study Group without Tramadol

DISCUSSION

In 1971, in Germany, a narcotic drug, Tramadol hydrochloride was introduced and it is available throughout the world. Analgesic effect of 100 mg tramadol hydrochloride administered intramuscularly is equivalent to that of 10 mg morphine or 100 mg pethidine, administered intramuscularly as obstetric analgesia.⁹ Tramadol, a weak opioid analgesic which purely exhibits agonist effects and interacts with μ, δ, κ opioid receptors. In the present study, the efficacy of intramuscular injection tramadol as labour analgesia and labour accelerator when administered to 50 selected primigravida in active stage of labour based on inclusion criteria was evaluated. The intensity of pain relief was assessed by asking the patient the extent and degree of pain relief.

In 1948, Hewer & Keele described grades of Analgesia as:¹⁰

- No pain -- Grade-I
- Slight pain but comfortable -- Grade-II
- Moderate pain with discomfort -- Grade-III
- Maximum pain or severe pain Grade -- Grade-IV

In the present study, before administration of intramuscular injection tramadol to 50 selected primigravida, no patient had grade-I or grade II pain, 30% patient had grade-III pain and 70% patient had grade-IV i.e. maximum pain. There was reduction of pain from grade IV and grade III to grade II in all 50 patients after administration of 50 mg tramadol intramuscularly. The other 50 women had grade III or grade IV pain throughout without administration of injection tramadol. This has proved the efficacy of tramadol as labour analgesia and it has decreased the intensity of pain. Similar study was conducted by Usha Rani Sharma, Verma RS in 1997, they compared tramadol to a no drug group. They concluded that tramadol was an effective analgesic without any significant maternal or neonatal

complications and that it can be safely administered during labour.¹¹ In 2000, the study was conducted by Fieni S, Angeri F et al to know the efficacy and tolerability of the two opioids usually used for parenteral analgesia to reduce labour pain - tramadol and meperidine and concluded that tramadol has good analgesic effect with better tolerability for the absence of collateral effects on the mother fetus and newborn. In 2001, similar study was conducted by Singh S et al to compare the effects of 100 mg tramadol with 30 mg pentazocine as labour analgesics. 60 women without any maternal or fetal complications were included in the study. They observed that pain relief with tramadol was 80%, pentazocine was 60%. Moreover, the maternal and fetal complications were slightly more in the pentazocine group.¹²

In present study, patients who delivered vaginally, statistically significant difference was found between two groups (with tramadol and without tramadol) when compared for the period of time from analgesic administration to the actual birth. In our patients with tramadol no statistical difference was found in the neonatal outcome compared to the other group without tramadol. Minimum side effects of tramadol was observed and there was no significant change in maternal vital parameters thus proving safety of tramadol as an obstetric analgesic. Tramadol is quite effective as labour analgesia and overall duration of labour is significantly reduced. There are minimal maternal side effects without any fetal or neonatal respiratory depression. In 2004, Dr. Nagesh Kumar conducted a randomized, prospective study on 100 women in labour. 50 women receiving tramadol and 50 women distilled H₂O. He concluded that IM tramadol can be used as safe labour analgesic in any health centres even with least monitoring facilities unlike other opioids because of negligible side effects at therapeutic dose either on mother/fetus. There was also significant shortening of duration of labour in tramadol group.¹³

CONCLUSIONS

It was found that tramadol was a safe and satisfactory drug for relief of labour pain. Thus, the maternal psychological attitude was improved and better tolerance instituted in these mothers with no adverse effects in the mothers or on to newborn. Hence, it can be concluded that the degree of

pain and duration of labour is significantly reduced in patients who are administered tramadol hydrochloride.

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