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Research Article

Effect of intramuscular tramadol hydrochloride as a labor analgesic in primigravidae

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ABSTRACT

Background: Labour pain is among the most severe pain experienced by women. The need for analgesia to overcome pain in labour is highly requested by women today. In developing nations where availability of facilities is the main limiting factor, intramuscular opioids can be considered.

Methods: This study was conducted in teaching. 200 low risk primigravidae who fulfilled the selection criteria with full-term pregnancy with vertex presentation with good uterine contractions and already in active phase of labour were given 100 mg tramadol hydrochloride intramuscularly.

Results: 200 primigravidae before giving the drug, no patient had grade-I or no pain, 19% had grade-III and 81% had grade-IV pain. After administration of tramadol hydrochloride IM there was reduction of pain from grade-III and grade IV by 52.49% and all of the patients continued with grade-II pain in 2nd stage and delivered normally and only 6 women had minimal side effects like nausea and vomiting.

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

Keywords: Labor analgesia, Tramadol hydrochloride intramuscular

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.¹ Labour and delivery cause pain in most patients. Nulliparous women are more likely to experience severe pain than multiparous women.² Pain of labour is rarely surpassed and frequently exceeds the woman's antepartum expectation. Rickford and Regnolds suggest that it is not that women underestimate the pain but tend to overestimate their ability to cope with it.³

The need for analgesia to overcome pain in labour is highly requested by women today. Various ways either non-pharmacologic e.g., emotional sustain, psychoprophylactic preparation, yoga and hypnosis or pharmacologic such as epidural blockade or parenteral

are used.⁴ Labour can be both physically and psychologically stressful for a woman and the resulting detrimental effects on the fetus are well documented.⁵ And adequate analgesia during labour is of benefit to the mother and has a positive influence on the course of labour and the state of newborn child. Thus making obstetrical analgesia an essential part of modern obstetrics.⁶

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.⁷

An ideal analgesic technique used should be cheap, easy to administer, produce good and reliable relief from pain but not impair consciousness/ cooperation. It should be not toxic to mother and fetus and not produce cardiorespiratory depression in the fetus. The technique must have no tocolytic action and not delay labour.⁸

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 awareness, trained staff and monitoring facilities and injectable opioids such as meperidine and tramadol are reasonably used.⁹ 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.¹⁰

METHODS

Source and data collection

200 primigravid women presenting with full term pregnancy at Tertiary care hospital

Inclusion criteria

All primigravid women presenting with:

- Full term pregnancy
- Vertex presentation
- Singleton live fetus
- In active phase of labour with engaged head for vaginal delivery.

Criteria for active labour

- 3-5 cm of cervical dilatation
- Fully effaced cervix
- Good uterine contractions i.e., contractions lasting for at least 25-30 seconds and 3 such contractions in a period of 10 min.

Exclusion criteria

- Parturients with any associated history of medical disorders.
- Any associated obstetrical complication with multiple gestation, APH, placenta previa, IUGR, CPD, epilepsy, psychiatric disorders
- History of hypersensitivity to drug.

Once the patient is in established active phase of labour i.e., ≥ 3 cms dilatation, full effacement with good uterine contractions, vital signs recorded and primary investigations done and pain score was noted before administering the drug. Injection tramadol 100 mg IM was given as a single dose depending on condition of the patient i.e., 2 mg/ Kg/ body weight. Pulse rate, respiratory rate, blood pressure, FHR were recorded. Patient was advised to inform as soon as pain begins to decrease in

intensity or even if there is no pain relief at all. Partogram was marked to assess the progress of labour.

The following observations were recorded:

1. Onset of action of the drug
2. Drug side effects, change in vital parameters at first every 30 min, then at hourly were monitored.
3. FHR monitoring was done clinically and any variability noted.
4. Progress of labour was monitored clinically.
5. Assessment of analgesia was done hourly by scoring system, injection repeated every 3 hours, not exceeding 400 mg/ day.
6. Patient level of consciousness, alertness, and psychological disturbances was judged.
7. The duration of labour, degree of pain relief in first and 2nd stage, the total dose of tramadol given, the mode of delivery and recovery time in each patient was noted and recorded.
8. Apgar score at 1 and 5 minutes interval after delivery of neonate was recorded.
9. Any complications during the course of labour were recorded. Patient was observed for 2 hours after delivery and was shifted to the ward if there were no complications.

Assessment of pain relief

The degree of pain relief was assessed in the following manner.

It is almost impossible to comprehend the degree of pain and agony women endure during delivery. It's a challenge to measure pain. Various methods exists, but none, which can guarantee pain measurement conclusively. During the course of this study pain relief after administration of the drug was analyzed and recorded using the rupees scale.

Rupees scale

The degree of pain relief was expressed as percent of the whole rupee. The degree of pain was graded as shown below:

Grade-I No pain.....	0
Grade-II Mild pain but comfortable.....	25%
Grade-III Moderate pain with discomfort.....	50%
Grade-IV Maximum pain / severe pain.....	$\geq 75\%$

RESULTS

In this study, 200 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 newborn.

Table 1: Showing the age group of women in the study group.

Age group (in years)	No. of women	Percentage
15-19	47	23.5
20-24	121	60.5
25-29	29	14.5
30-34	03	1.5
Total	200	100

From the above, maximum of 60.5% are in the age group of 20 to 24 years and 23.5% are in the age group of 15 to 19 years. About 14.5% are in the age group 25 to 29 years and 1.5% is in the age group 30 to 34 years.

Mean age of women in the study: 22.03 years.

Standard deviation: 3.31 years

95% confidence limits for age: (21.56 years, 22.49 years).

Table 2: Summary of statistical analysis of study.

Variables	Mean value	Standard deviation	95% Confidence interval
Age in years	22.03	3.31	(21.56, 22.49)
EFW in Kg	2.79	0.42	(2.73, 2.85)
Duration of labour			
Stage I	3.72	2.22	(3.41 h, 4.03h)
Stage II	20.46	11.38	(18.88, 22.04)
Stage III	5.595 minute	2.310	(5.27 sec, 5.91 sec)
Injection delivery interval (hours)	1.76	1.18	(1.59 hour, 1.92 hours)
Pain score			
Before admission of drug			
Stage I	3.81	0.39	(3.75, 3.86)
After admission of drug			
Stage I	2.00		
Stage II	2.00		

Before administration of drug at stages I, maximum patients i.e. 162 81% are having grade IV type of pain. After administration of drug maximum patients i.e. 200 (100%) having grade II type of pain. The mean degree of pain before administration of drug is 3.81 ± 0.39 . After administration of drug the mean degree of pain is 2. The mean reduction of pain is 52.49%.

DISCUSSION

The ACOG 2002b recently reaffirmed its position published jointly with the American Society of Anaesthesiologists that a request for pain relief by the woman is sufficient medical indication for its use.¹¹

Table 3: Degree of pain relief.

Degree of pain	Before admn of drug stage I	After admn of drug stage I	After admn of drug stage II
Grade I	0	0	0
Grade II	0	200 (100%)	200 (100%)
Grade III	38 (19%)	0	0
Grade IV	162 (81%)	0	0
Total	200	200	200
Mean degree of pain	3.81	2.00	2.00
SD of pain	0.39	-	-
95% CI for mean degree of pain	(3.75, 3.86)	-	-

In a scholarly review Lowe, emphasized that the experience of labour pain is a highly individual reflection of variable stimuli that are uniquely received and interpreted by each woman individually.¹²

Heever and Kell described the technique of pain score for assessment of the efficacy of the various forms of analgesia. It is hard to compare the analgesic effects of the drugs since it depends on subjective evaluation of the pain. However studies indicated tramadol as an effective analgesic that can be used for the treatment of intense acute and chronic pain such as postoperative and obstetric pain.¹³

Tramadol hydrochloride, a narcotic drug introduced in Germany is 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.¹⁴

Tramadol is a weak opioid analgesic, which interacts with μ , δ , κ opioid receptors, where it exhibits purely agonist effects.¹⁵

In the present study, the effect of intramuscular tramadol when given to 200 primigravid woman in labour of age 18 – 35 years were studied. Similar studies were conducted earlier.

One was by Jain S, Arya VK et al at the Department of Obstetrics & Gynecology and Department of Anesthesia, Post Graduate Institute of Medical Education & Research, Chandigarh, India during 2003, where intramuscular tramadol and intramuscular meperidine were compared with epidural analgesia. Another similar study was carried out by Thakur Ratna, Patidar Rekha, Department of Obstetrics & Gynecology, MGM Medical College and MY Hospital, Indore, India.

Age incidence

In our study, there was no significant variation in the age incidence.

Table 4: Comparison of age with Keskin et al.¹⁶

	Keskin et al (IJGO) ¹⁶	Present study
Mean age	22.43	22.03

From the above table, it can be observed that the mean age is comparable with the study of Keskin et al.

Mode of delivery

In the present study 100% of patients had full-term normal delivery, wherein the study conducted by Thakur Ratna and Meena Jyoti, Singhal Prabha et al showed 98% full-term normal delivery and 2% with forceps delivery. Injection oxytocin and injection drotine was used wherever necessary.

Table 5: Comparative analysis of mode of delivery.

Mode of delivery	Thakur Ratna ¹⁷ IJOG	Keshin ¹⁶ IJOG	Prasert-sawat ¹⁸ CTR	Sarkar ¹⁹ IJOG	Bajaj ²⁰ IP	Hussein Gerburtsh, Perinatol ²¹	Prabha Singhal JOGI ²²	Present study
FTND	98	57	93	72	82	79	98	200
LSCS	--	2	2	8	10	3	--	--
Ventose	--	--	5	--	3	10	--	--
Forceps	2	--	--	20	5	8	2	--
Total	100	59	100	100	100	100	100	200

Mode of delivery was comparably good enough to the other standard studies of the series, where the incidence of operative deliveries had decreased with the use of tramadol.

Effectiveness of analgesia and degree of pain relief

There is no doubt that labor pain is one of the most intense pains experienced but the perception of pain varies strikingly between individuals.¹⁵

Out of 200 patients in the present study before giving the drug, no patient had grade-I or no pain, 19% had grade-III and 81% had grade-IV i.e., maximum pain.

After administration of 100 mg tramadol intramuscularly in the first stage, there was reduction of pain from grade III and IV to grade II i.e. by 52.49% in 200 patients and these 200 patients continued in the second stage with grade-II pain. This assessment holds well with studies conducted by Thakur Ratna, etc.

Table 6: Comparative analgesic of pain relief.

Degree of pain relief	Thakur ratna ¹⁷ IJOG	Prasertsa wat CTR ¹⁸	Bajaj IP ²⁰	Hussein Gerburtsh perinatol ²¹	Sarkar Jogi ¹⁹	Prabha Singhal JOGI ²²	Present study
No relief	14	22	20	1	2	0	--
Mild relief	16	--	33	20	47	14	--
Moderate satisfactory relief	55	53	38	49	38	32	200
Complete relief	15	25	9	30	13	54	--
Total	100	100	100	100	100	100	200

Pain relief was comparably good enough to the other standard study of the series where there was a moderate relief of pain in the present study as compared to the

other studies mentioned above. All the patients 200 (100%) in our study group had pain relief as only comparable to the closest compares Hussein (99%), Sarker (98%), Veiges (91%).

This has proved beyond doubt that tramadol has very good efficacy as analgesia in labour and it has decreased the intensity of pain in both 1st and 2nd stage of labour.

CONCLUSIONS

In the 1st stage degree of pain has significantly reduced from severe and moderate pain to mild pain in most of the subjects and in the 2nd stage, the degree of pain continued to be mild. It was found that tramadol was a safe and satisfactory drug for relief of labour pain.

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