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Tramadol: Is It Still Relevant As A Labour Analgesic

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Abstract

A prospective randomized single blinded controlled study conducted in 200 primigravidae in active labor, distributed in two groups of 100 women each with one receiving 100mg intramuscular tramadol and the other receiving intramuscular 2 ml distilled water as control. Pain intensity was recorded by McGills scale before, one and three hours after drug administration and perinatal outcome recorded. No difference in pain intensity seen before drug administration. After 1 hour, of drug administration, in tramadol group 4% women had horrible pain and 29% had distressing pain while in control group, 30% women had horrible pain and 60% had distressing pain. After 3 hours, of drug administration, in tramadol group 26% had distressing pain while in control group, 51% women had horrible pain and 35% had distressing pain. Labor duration in tramadol and control group was 4.3 and 5.9 hours respectively. In control group, nausea seen in 2.2%, vomiting in 1.1% while in tramadol group nausea seen in 6.4% and vomiting in 4.3%. Neonatal outcome was favourable in both the groups. Intramuscular tramadol is an effective labor analgesic with few maternal adverse effects, shortens labor and has no adverse neonatal outcome.

Keywords – Intramuscular Tramadol, labor , intrapartum, analgesia

INTRODUCTION

Labor pain is among the most severe pain experienced by woman. The McGill Pain Questionnaire ranks labor pain in the upper part of scale between that of cancer pain and amputation of digit. Pain causes apprehension, anxiety and stress which leads to increased sympathetic activity which causes prolonged labor and so adverse outcome experience has shown that providing pain relief during labor reduces maternal stress and results in shorter labor and improved maternal and fetal outcome1. Obstetric analgesia is a desired component of the process of labor to make motherhood really safe. With change of attitude in modern times, pain free labor has become a very real expectation. Most of modern obstetric analgesic practices involve participation of expert anaesthesiologist. In developing countries, where majority of obstetric services are in the hands of midwives, trained nurses and non-specialized doctors, a method with minimal technicality is desired. 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 and not produce cardio-respiratory depression in the fetus. The technique must have no tocolytic action and not delay labor. 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 hydrochloride are reasonably used2.

This study is conducted with the aim of testing analgesic potency, merits, demerits and outcome of intramuscular Tramadol hydrochloride during labor so that it can be widely used to improve safety as well as quality of motherhood. Aim of the present study was to study the effect of Tramadol hydrochloride on duration of labor, to assess degree of pain relief scores, to study neonatal outcome after use of Tramadol hydrochloride and to compare the incidence of operative intervention (caesarean section) with and without use of Tramadol hydrochloride.

MATERIAL AND METHODS

The present study was a prospective randomized study conducted in the 200 primigravidae women were admitted in the labor room of Department of Obstetrics and Gynaecology during the year 2013, at SHKM, Medical College, Haryana. Primigravida with full term pregnancy in age group 20-35 years with single fetus with vertex presentation in active phase of labor were included in the study. Active phase of labor was described as cervical dilatation more than or equal to 3 cm, cervical effacement more than or equal to 60% and with good uterine contractions i.e. 3 contractions in every 10 minutes lasting for 30-45 seconds. Women with associated medical disorder, any obstetrical complications and history of allergy to any opioid or hypersensitivity to drug were excluded from the study. After taking informed consent the women were randomly distributed in two groups, study group - 100 women and control group -100 women.

All the women in the study group were given Injection Tramadol hydrochloride 100mg intramuscularly single dose and all the women in control group received 2ml of placebo (distilled water).Pain intensity before administering drug, at 1 hour and three hours of drug administration was recorded by McGills pain intensity scale (Table 1).

TABLE 1.MC GILLS PAIN INTENSITY SCALE

Mc Gills Scale	Pain Intensity
0	No pain
1	Mild pain
2	Discomfort
3	Distressing
4	Horrible
5	Excruciating

Drug side effects, change in vital parameters at first every 30 minutes, and then at hourly interval were monitored along with maternal and fetal outcome. Data was described as mean+SD and percentage. Metric data was compared by Student's t test where as Non-metric data was compared by Chi-square test and Mann Whitney U tests. $p<0.05$ was considered as significant p value. Software used was Microsoft Excel and Statistical Package for Social Sciences (SPSS 11.5) for data analysis.

RESULTS

The mean age of the women in the study group was 26.0+2.8 years and in the control group was 26.1+2.6 years. The difference was not statistically significant between the two groups (p = 0.399).

The mean gestational age in the study group was 38.8+1.0 weeks and in the control group was 38.7+1.0 weeks. The difference was statistically insignificant between the two groups (p= 0.340).

The mean dilatation and effacement of cervix in the study group was 4.1+0.9cm and 78.1+11.5% respectively. In the control group, the mean dilatation and effacement of cervix was 4.1+0.8cm and 77.0+10.6% respectively. The difference was not statistically significant between the two groups (p= 0.678 and p=0.483).

Using McGills pain intensity scale 31 (31%) women in the study group had horrible pain, 66 (66%) women had distressing pain and 3 (3%) women had discomfort at the point of entry into the study (Table 2).

In the control group, 16 women (16%) had horrible pain, 78 women (78%) had distressing pain and 6 women (6%) had discomfort. The pain intensity using McGills scale between the two groups before drug administration was statistically insignificant (p= 0.010) (Table 2).

After 1 hour of drug administration 4 women (4%) had horrible pain, 29 women (29%) had distressing pain, 57 women (57%) had discomfort and 10 women (10%) had mild pain (Table 2).

In the control group, 30 (30%) women had horrible pain, 60 (60%) had distressing pain, 8 (8%) women had discomfort and 2 (2%) women had mild pain after 1 hour of drug administration. The difference in the two groups was statistically significant (p=0.000) (Table 2).

TABLE 2. Pain Intensity of the Studied Subjects Using McGills Scale

Time	Pain Intensity	Study Group		Control Group		p value
		n	%	n	%	
Before Drug Administration	Mild	0	0.0	0	0.0	0.010 (NS)
	Discomfort	3	3.0	6	6.0	
	Distressing	66	66.0	78	78.0	
	Horrible	31	31.0	16	16.0	
After 1 hr of Drug Administration	Mild	10	10.0	2	2.0	0.000 (Sig)
	Discomfort	57	57.0	8	8.0	
	Distressing	29	29.0	60	60.0	
	Horrible	4	4.0	30	30.0	
After 3 hrs of Drug Administration	Mild	33	33.0	7	7.0	0.000 (Sig)
	Discomfort	41	41.0	7	7.0	
	Distressing	26	26.0	35	35.0	
	Horrible	0	0.0	51	51.0	

After 3 hours of drug administration, 26 (26%) women had distressing pain, 41 (41%) women had discomfort, and 33 (33%) women had mild pain in the study group. In the control group, 51 woman (51%) had horrible pain, 35women (35%) had distressing pain, 7 women (7%) had discomfort and 7 (7%) women had mild pain using McGills pain intensity scale. The difference between the two groups was statistically significant (p=0.000) (Table 2).

Women who had LSCS were excluded for comparison of duration of labor. 6 women in the study group had LSCS, 8 women in the control group had LSCS.

The mean duration of the active phase of first stage of labor in the study group was 222.2+40.9 minutes and in the control group was 308.7+37.7 minutes (Table 3).

The difference in the mean duration of the active phase of first stage of labor between the study and control groups was statistically significant (p= 0.000) (Table 3).

The mean duration of the second stage of labor in the study group was 33.2+6.8 minutes and in the control group was 42.3+9.2 minutes (Table 3).

The difference in the mean duration of second stage of labor between the study and control group was statistically significant (p= 0.000) (Table 3).

The mean duration of third stage of labor in the study group was 5.1+1.3 minutes and in the control group was 8.7+2.9 minutes. The difference in the mean duration of third stage of

labor in the two group was statistically significant (p= 0.000) (Table 3).

TABLE 3. Duration of Labour(min) of the Studied Subjects

	Study Group (Mean+SD, Range)	Control Group (Mean+SD, Range)	p value
First Stage of Labour (min)	222.2 ± 40.9 (170, 314)	308.7 ±37.7 (216, 379)	0.000 (Sig)
Second Stage of Labour (min)	33.2 ± 6.8 (20, 50)	42.3 ± 9.2 (25, 70)	0.000 (Sig)
Third Stage of Labour (min)	5.1 ± 1.3 (3,10)	8.7 ± 2.9 (5, 19)	0.000 (Sig)
Total Duration of Labour (min)	260.5 ± 41.3 (206, 358)	359.7 ± 44.3 (266, 442)	0.000 (Sig)
Injection Delivery Interval (hr)	3.0 ± 1.3 (1, 5)	3.6 ± 1.3 (1, 5)	0.001 (Sig)

Total duration of labor from enrolment in study to delivery in the study group was 260.5+41.3 minutes and in the control group was 359.7+44.3 minutes. The difference was statistically significant between the two groups (p= 0.000) (Table 3).

Injection delivery interval in the study group was 3.0+1.3 hours and in the control group was 3.6+1.3 hours. The difference in the two groups was significant (p= 0.001).

94 (94%) women in the study group and 92 (92%) women in the control group had spontaneous vaginal delivery. 6 (6%) women in the study group and 8 (8%) women in the control group had to undergo lower segment caesarean section (LSCS). There was no instrumental vaginal delivery in both groups. No statistically significant difference in the mode of delivery was found between the two groups p= 0.580 (p > 0.05).

The mean Apgar score of neonates in the study group at 1 minute was 7.7+1.2 and at 5 minutes was 9.6+0.8.

The mean Apgar score of the neonates in the control group at 1 minute was 7.8+1.2 and at 5 minutes was 9.7+0.7. The difference was statistically insignificant (p=0.636, 0.204).

The mean birth weight was 2.9+0.2kg in the study group and 2.8+0.2kg in the control group. The difference was statistically insignificant (p= 0.123) between the two groups.

Nausea was the most common side effect seen in the study group (6.4%) followed by vomiting (4.3%). In the control group, nausea was seen in 2.2% followed by vomiting in 1.1%. No women in the study and the control group had respiratory depression, PPH and fetal tachycardia/bradycardia. The difference in the

side effects was statistically insignificant between the two groups ($p > 0.05$) (Table 4).

TABLE 4. Comparison of Maternal Side Effects / Complications in the Studied Subjects

Maternal Side Effects	Study Group		Control Group		p value
	n	%	n	%	
Nausea	6	6.4	2	2.2	0.157 (NS)
Vomiting	4	4.3	1	1.1	0.182 (NS)
Respiratory Depression	0	0.0	0	0.0	1.000 (NS)
Fetal Tachycardia/ Bradycardia	0	0.0	0	0.0	1.000 (NS)
Post partum haemorrhage	0	0.0	0	0.0	1.000 (NS)

DISCUSSION

"The delivery of an infant into the arms of conscious and pain free mother is one of the most exciting and rewarding moments in Medicine." 3 Labor is a physiological but painful event. The distress and agony which often women endure during labor is certainly beyond description. Adequate analgesia during labor is a benefit for the mother, has a positive influence on the course of labor and the state of newborn child. The use of techniques and medications to provide relief in labor pain requires an expert understanding of their effects to ensure the safety of both mother and neonate.

Tramadol hydrochloride, a narcotic drug introduced in Germany is available throughout the world. Tramadol hydrochloride is a synthetic analogue of codeine that binds to mu opiate with low affinity receptors and inhibits nor-epinephrine and serotonin reuptake. It has no clinically significant respiratory depression at usual doses of 1-2 mg/kg body weight. The onset of action is Within 10 min of intramuscular administration, reaches peak at 45 minutes and the duration lasts for approximately 2-3 h. In obstetric analgesia 100mg of Tramadol hydrochloride administered intramuscularly has an analgesic effect equivalent to that of 100mg pethidine or 10mg Morphine administered intramuscularly.4 Claahsen-van der Grinten demonstrated a high placental permeability for tramadol. However, neonates possess complete hepatic capacity to metabolize tramadol. Compared with pethidine, mothers receiving tramadol had higher pain scores.5 Therefore; crossover to alternate methods of relief is very common.

The study group had a significant decrease in pain intensity after drug administration as compared to control group. 75% women in the study group had substantial relief of pain. Thus the pain relief in our study is consistent with the studies by Doshi et al, Nagariaet al and Bajaj et al.6-8

There was statistically significant reduction in duration of first, second and third stages of labor after giving Tramadol hydrochloride. The total duration of labor was significantly less in the study group as compared to that in the control group. Similar results have been reported by other studies. Shortened duration of labor could be a very encouraging parameter as it would decrease dysfunctional labor and associated with a better perinatal outcome.9, 7

There was also no increase in the operative delivery rate in cases where Tramadol hydrochloride was used.6, 7

There was no adverse effect on neonatal outcome. There was no change in fetal heart rate, there was no still births or neonatal death in the study group. Thus, the Apgar score in our study was consistent with what has been reported in other studies.10, 7

In our study, minor side effects like nausea, vomiting was seen in women in both the study and control group. The difference was statistically insignificant between the two groups. No major complication was seen in either group. No patient complained of headache, dizziness, sedation, dry mouth, respiratory depression, PPH or any other side effects.

There were no adverse effects on pulse, blood pressure, respiratory rate, uterine action or bearing down efforts. This clearly shows the safety of Tramadol hydrochloride as analgesic when used in labor.

CONCLUSION

Thus the study concluded that Tramadol hydrochloride given intramuscularly in active labor offers good labor analgesia without any adverse effects on maternal and fetal vital parameters and is of special interest in low resource settings of the developing nations.

REFERENCES

1. Veronia IY, Kaur V, Kaur D. Programmed labor for optimisizing labor and delivery. JK science 2008 Jun; 10(2).
2. Jain S, Arya VK, Gopalan S, Jain V. Analgesic efficacy of intramuscular opioids versus epidural analgesia in labor. Int J Gynaecol Obstet 2003 Oct; 83(1): 19-27.
3. Mimanik. Recent evidences in the pharmacological mechanism of the Tramadol 2005; 54: 1224-33
4. Vickers MD, Oflaberty D, Szekely SM. Tramadol: pain relief by an opioid without depression of respiration.Anaesthesia 1992; 47: 291-296.
5. Claahsen-van der Grinten HL, Verbruggen I, van den Berg PP, Sporken JM, Kollée LA. Different pharmacokinetics of tramadol in mothers treated for labor pain and
6. in their neonates. Eur J Clin Pharmacol. 2005;61(7):523-9.
7. Doshi HU, Oza H, Maheshwari S et al. Role of Tramadol in labor analgesia. Obs and Gynae Today 2007; 12: 500-502.
8. Nagaria T, Acharya J. Pain relief in labor-Tramadol versus Pentazocine. J Obstet Gynaecol India 2006 Sep-Oct; 56(5): 406-409.

9. Bajaj P, Meena R, Prasad R. Intravenous Tramadol for labor analgesia. The Indian Practioner, 1997; 50(12): 1051-1054.
10. Meena J, Singhal P, Choudhary D. Progammed labor. J Obstet Gynaecol India 2006 Jan-Feb; 56(1): 53-55.
11. Thakur R, Patidar R. Comparative study of transcutaneous electrical nerve stimulation and Tramadol hydrochloride for pain relief in labor. J Obstet Gynaecol of India 2004 Jul-Aug; 54(4): 346-350.