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Original Research Article

Relief of Labour Pain with Single Dose of Tramadol Hydrochloride

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ABSTRACT

Aim: To study the efficacy of Tramadol Hydrochloride as an analgesic in labour pain and to assess its effects on maternal and fetal health.

Study Design: Prospective, hospital based.

Subjects and Methods: A study was conducted on 200 pregnant females in the Department of Obstetrics and Gynaecology during the year 2010-2011, at Government Lalla Ded Hospital, Srinagar associated with Government Medical College, Srinagar, Jammu and Kashmir. Primigravidae with full term pregnancy in the age group of 20-35 were studied among the women admitted in the labour room.

Results: 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. There was statistically significant reduction in duration of first, second and third stages of labour after giving Tramadol hydrochloride. The total duration of labour was significantly less in the study group as compared to that in the control group. There was no increase in the operative delivery rate in cases where Tramadol hydrochloride was used. There was no adverse effect on neonatal outcome. There was no change in fetal heart rate; there was no still birth or neonatal death in the study group. The maternal morbidity was much less. Nausea and vomiting were only side effects observed after administration of Tramadol hydrochloride.

Conclusion: Tramadol hydrochloride given intramuscularly in active labour offers good labour analgesia without any adverse effects on maternal health and fetal vital parameters.

Keywords: Tramadol, Labour Pain, Analgesia.

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INTRODUCTION

Labour pain is among the most severe pains experienced by woman. The distress and agony which often women endure during labour is certainly beyond description. Human parturition has been termed as 'labour' in recognition of the hard work that the parturient as well as the uterine myometrium have to perform in order to deliver the fetus.[1]

The McGill Pain Questionnaire ranks labour pain in the upper part of scale between that of cancer pain and amputation of digit. Melzack et al also demonstrated that severity of labour pain varies greatly with nulliparous women experiencing greater pain.[2]

The concept of providing relief from pain has been tardy in acceptance, however experience has shown that providing pain relief during labour reduces maternal stress and results in shorter labour and improved maternal and fetal outcome.[3] With change of attitude in modern times, pain free labour has become a very real expectation.

A variety of methods are available with their own advantages over each other. Most of modern obstetric analgesic practices involve participation of expert anaesthesiologist. In India, where majority of obstetric services are in the hands of midwives, trained nurses and non-specialised 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 labour.

The need for analgesia to overcome pain is highly requested by women. Various ways either non-pharmacological like emotional sustain, psycho-prophylactic preparation, yoga and hypnosis or pharmacological such as epidural blockade or parenteral are used.[4] 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 used.[5] Tramadol hydrochloride is a synthetic analogue of codeine that binds to 'μ' (mu) opiate receptors and inhibits nor-epinephrine and serotonin reuptake.[6] Tramadol hydrochloride was developed by Grunenthal in 1962 and was first launched in Germany in 1977. Since then it has been extensively used for relieving moderate to severe pain in different situations.[7]

This study is conducted with the aim of testing analgesic potency, merits, demerits and outcome of intramuscular Tramadol hydrochloride during labour so that it can be widely used to improve safety as well as quality of motherhood.

MATERIALS AND METHODS

The present study was conducted in the Department of Obstetrics and Gynaecology during the year 2010-2011, at Government Lalla Ded Hospital, Srinagar associated with Government Medical College, Srinagar, Kashmir. Total of 200 women (Primigravidae) were studied among the women admitted in the labour room.

The criteria for selection of study and control group were as follows:

Inclusion Criteria

1. Primigravida with full term pregnancy and normotensive.
2. Age group 20-35 years.
3. Single live fetus with vertex presentation.
4. No cephalopelvic disproportion.
5. In active phase of labour.

Criteria for Active Phase of Labour

1. Cervical dilatation $\geq$ 3cm.
2. Cervical effacement $\geq$ 60%.
3. Good uterine contractions i.e. 3 contractions in every 10 minutes lasting for 30-45 seconds.

Exclusion Criteria

1. Any associated medical disorder.
2. Any obstetrical complications like placenta praevia, Intrauterine growth retardation, multiple gestation, Cephalopelvic disproportion, epilepsy, psychiatric disorders, Antepartum Haemorrhage.
3. History of allergy to any opioid or hypersensitivity to drug.

Method

Informed consent was taken from each patient who was enrolled in the study. The subjects were randomly distributed in two groups- study group and control group each carrying 100 patients.

All the patients of the study group were given Injection Tramadol hydrochloride 100mg intramuscularly single dose. The patients from control group received 2ml of placebo (distilled water).

Pain intensity before administering drug was recorded by McGills pain intensity scale.

In all women included in the study a detailed history, general physical examination and obstetric examination including vaginal examination was done and all the required investigations carried out.

The efficacy of Tramadol hydrochloride to relieve pain was analysed by using:

(a) Mc Gills Pain intensity Scale

(b) Oxford Pain relief Score

Mc Gills Pain Intensity Scale

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

Available at: https://www.ncbi.nlm.nih.gov/pubmed/1235985

Oxford Pain Relief Score

Oxford Score	Pain Relief
1	None
2	Slight
3	Moderate
4	Good
5	Complete

Cited from: Oxford Pain Relief Database 1950–1994

Drug side effects, change in vital parameters at first every 30 minutes, then at hourly interval were monitored.

Progress of labour was monitored clinically. Duration of three stages of labour (stage I, stage II and stage III) were recorded. Mode of delivery (Normal vaginal / instrumental vaginal / caesarean section) was noted. Assessment of neonatal outcome was recorded in all babies delivered in the study as well as control group using Apgar score at 1 minute and 5 minutes. Neonatal depression assessment from Apgar score:

8 – 10: No depression

6 – 7: Moderate depression

0 – 5: Severe depression

Maternal and fetal monitoring in terms of maternal pulse rate, blood pressure and respiratory rate as well as fetal heart rate were

recorded. Side effects or complications of drug if any were noted like nausea, vomiting, respiratory depression (respiratory rate < eight breaths/minute) and fetal distress (tachycardia/bradycardia). Any complications during course of labour was recorded.

Statistical Analysis: 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 test. $p<0.05$ was considered as significant p value. Software used was Microsoft Excel and Statistical Package for Social Sciences (SPSS 11.5) for data analysis.

Table 1: Age (Years) of the Studied Subjects

Age (Years)	Study Group		Control Group		p value
	n	%	n	%	
20 to 24	28	28.0	32	32.0	0.399
25 to 29	64	64.0	63	63.0	(NS)
30 to 34	8	8.0	5	5.0	
Mean ± SD, Range	26.0 ± 2.8 (20, 35)		26.1 ± 2.6 (20, 35)		

Table 2: Gestation Age (week) of the Studied Subjects

Gestation Age (week)	Study Group		Control Group		p value
	n	%	n	%	
37	14	14.0	18	18.0	0.340 (NS)
38	20	20.0	22	22.0	
39	38	38.0	36	36.0	
40	28	28.0	24	24.0	
Mean ± SD, Range	38.8 ± 1.0 (37, 40)		38.7 ± 1.0 (37, 40)		

Table 3: Dilatation (cm) and Effacement of cervix (%) at the time of enrolment in study

	Study Group (Mean±SD, Range)	Control Group (Mean±SD, Range)	p value
Dilatation of cervix (cm)	4.1 ± 0.9 (3, 6)	4.1 ± 0.8 (3, 6)	0.678 (NS)
Effacement of cervix (%)	78.1 ± 11.5 (60, 100)	77.0 ± 10.6 (60,100)	0.483 (NS)

Table 4: Pain Intensity of the Studied Subjects Using Mc Gills Scale

Time	Pain Intensity	Study Group		Control Group		p value
		n	%	n	%	
Before Drug Administration	Mild	0	0.0	0	0.0	0.010
	Discomfort	3	3.0	6	6.0	(NS)
	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
	Discomfort	57	57.0	8	8.0	(Sig)
	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
	Discomfort	41	41.0	7	7.0	(Sig)
	Distressing	26	26.0	35	35.0	
	Horrible	0	0.0	51	51.0	

Table 5: Pain Relief in the Studied Subjects Using Oxford Score

Time	Pain Relief	Study Group		Control Group		p value
		n	%	n	%	
After 1 hr of Drug Administration	None	36	36.0	64	64.0	0.000 (Sig)
	Slight	45	45.0	36	36.0	
	Moderate	19	19.0	0	0.0	
	Good	0	0.0	0	0.0	
After 3 hr of Drug Administration	None	25	25.0	77	77.0	0.000 (Sig)
	Slight	35	35.0	23	23.0	
	Moderate	33	33.0	0	0.0	
	Good	7	7.0	0	0.0	

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 >0.05).

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 >0.05).

Similarly there was no statistically significant difference in the mean dilatation and effacement of cervix between the study group and the control group.

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

In the control group, 16 patients (16%) had horrible pain, 78 patients (78%) had distressing pain and 6 patients (6%) had discomfort. The pain intensity using McGills scale between the two groups before drug administration was statistically insignificant (p >0.05).

After 1 hour of drug administration 4 patients (4%) had horrible pain, 29 patients (29%) had distressing pain, 57 patients (57%) had discomfort and 10 patients (10%) had mild pain in the study group.

While in the control group, 30 (30%) patients had horrible pain, 60 (60%) had distressing pain, 8 (8%) patients had discomfort and 2 (2%) patients had mild pain after 1 hour of drug administration. The difference in the two groups was statistically significant (p <0.05).

After 3 hours of drug administration, 26 (26%) patients had distressing pain, 41 (41%) patients had discomfort, and 33 (33%) patients had mild pain in the study group. In the control group, 51 patient(51%) had horrible pain, 35 patients(35%) had distressing pain, 7 patients(7%) had discomfort and 7 (7%) patients had mild pain using McGills pain intensity scale.

The difference between the two groups was statistically significant (p<0.05).

19 (19%) patients had moderate relief of pain, 45 (45%) patients had slight relief of pain and 36 patients (36%) had no relief of pain after 1 hour of drug administration in the study group using Oxford Pain Relief Score.

In the control group, 36 (36%) patients had slight pain relief and 64 (64%) patients had no pain relief after 1 hour of drug administration. The difference was statistically significant between the two groups (p < 0.05).

In the study group, 7 patients (7%) had good relief of pain, 33 patients (33%) had moderate relief of pain, 35 patients (35%) had slight relief of pain, and 25 patients (25%) had no pain relief after 3 hours of drug administration using Oxford Pain Relief Score.

In the control group, 23 patients (23%) had slight pain relief and 77 patients (77%) had no pain relief after 3 hours of drug administration using Oxford pain relief score.

The difference was statistically significant between the two groups (p < 0.05).

Women who had LSCS were excluded for comparison of duration of labour. 6 patients in the study group and 8 patients in the control group had LSCS.

The mean duration of the active phase of first stage of labour in the study group was 222.2±40.9 minutes and in the control group was 308.7±37.7 minutes.

The difference in the mean duration of the active phase of first stage of labour between the study and control groups was statistically significant (P < 0.05).

The mean duration of the second stage of labour in the study group was 33.2±6.8 minutes and in the control group was 42.3±9.2 minutes.

The difference in the mean duration of second stage of labour between the study and control group was statistically significant (p <0.05).

The mean duration of third stage of labour 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 labour in the two group was statistically significant (p < 0.05).

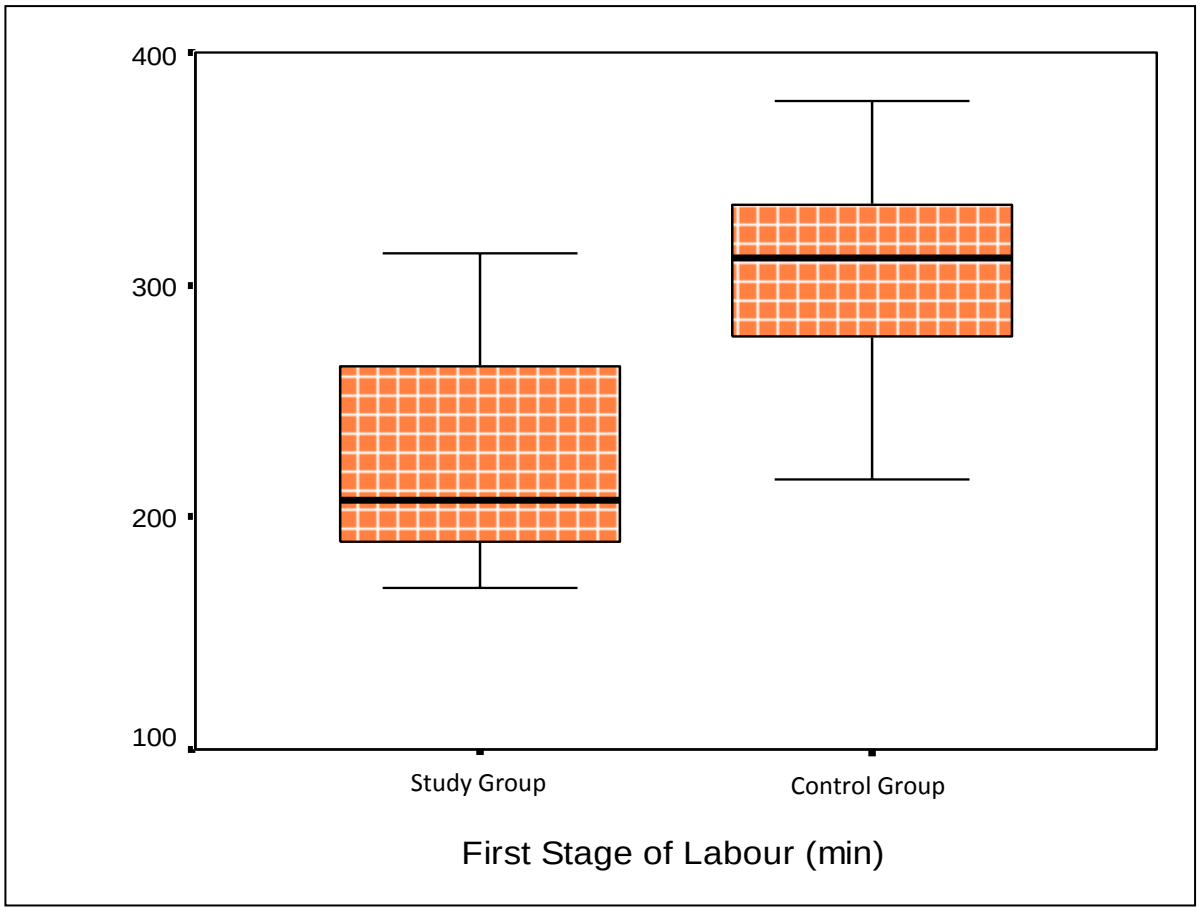
Total duration of labour from enrolment in study to delivery in the study group was 260.5±41.3 minutes and in the control group was 359.7±44.3 minutes. The difference was statistically significant between the two groups (p < 0.05).

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 < 0.05).

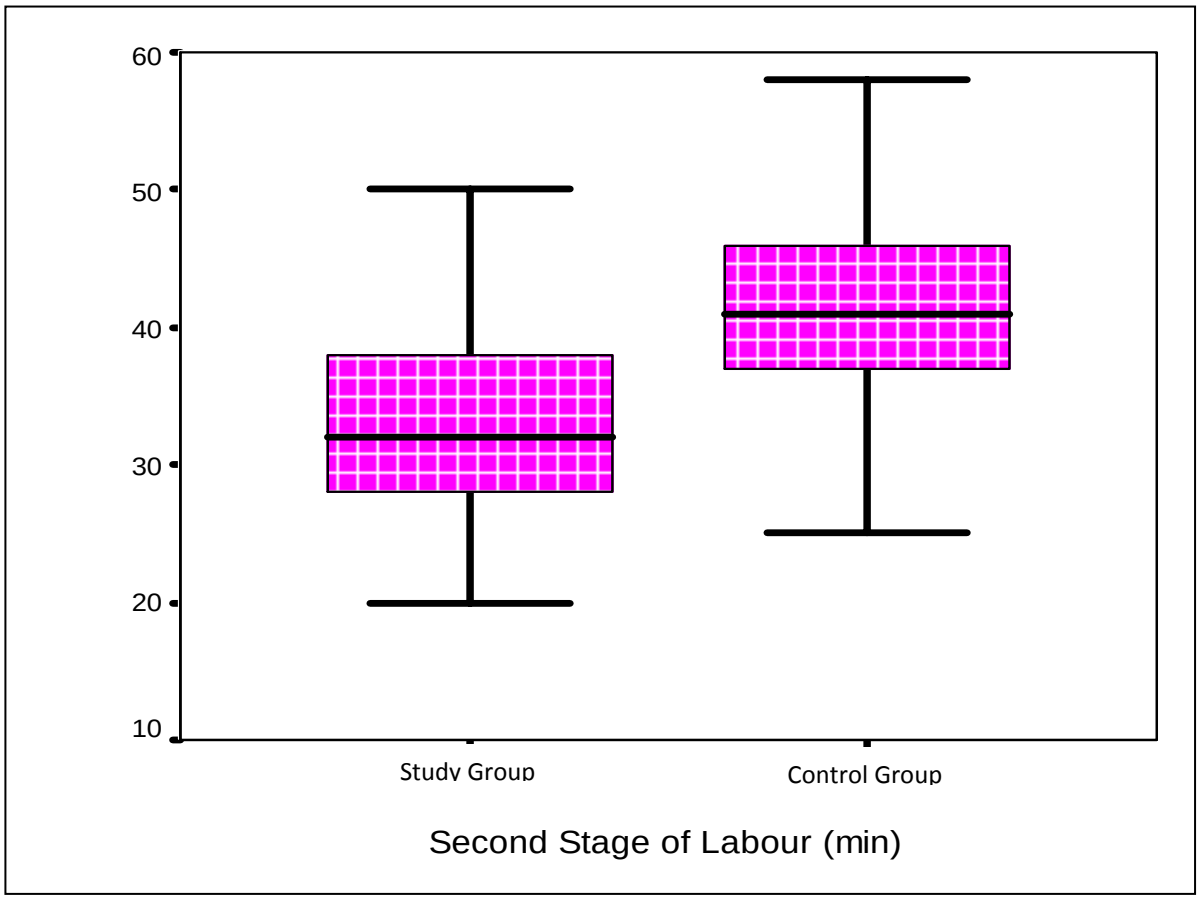
Table 6: Duration of Labour(min) of the Studied Subjects

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

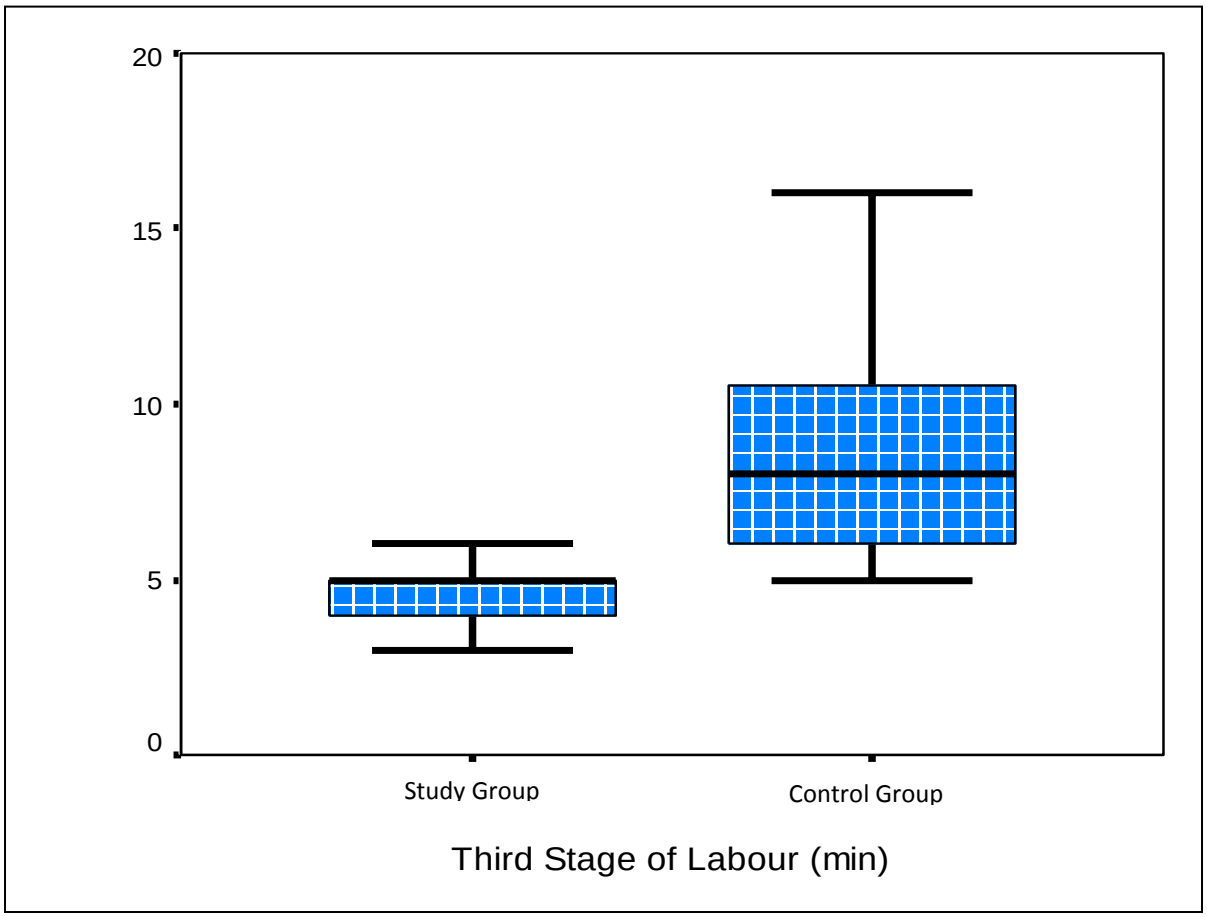
Duration of Labour [First Stage of Labour (min)]



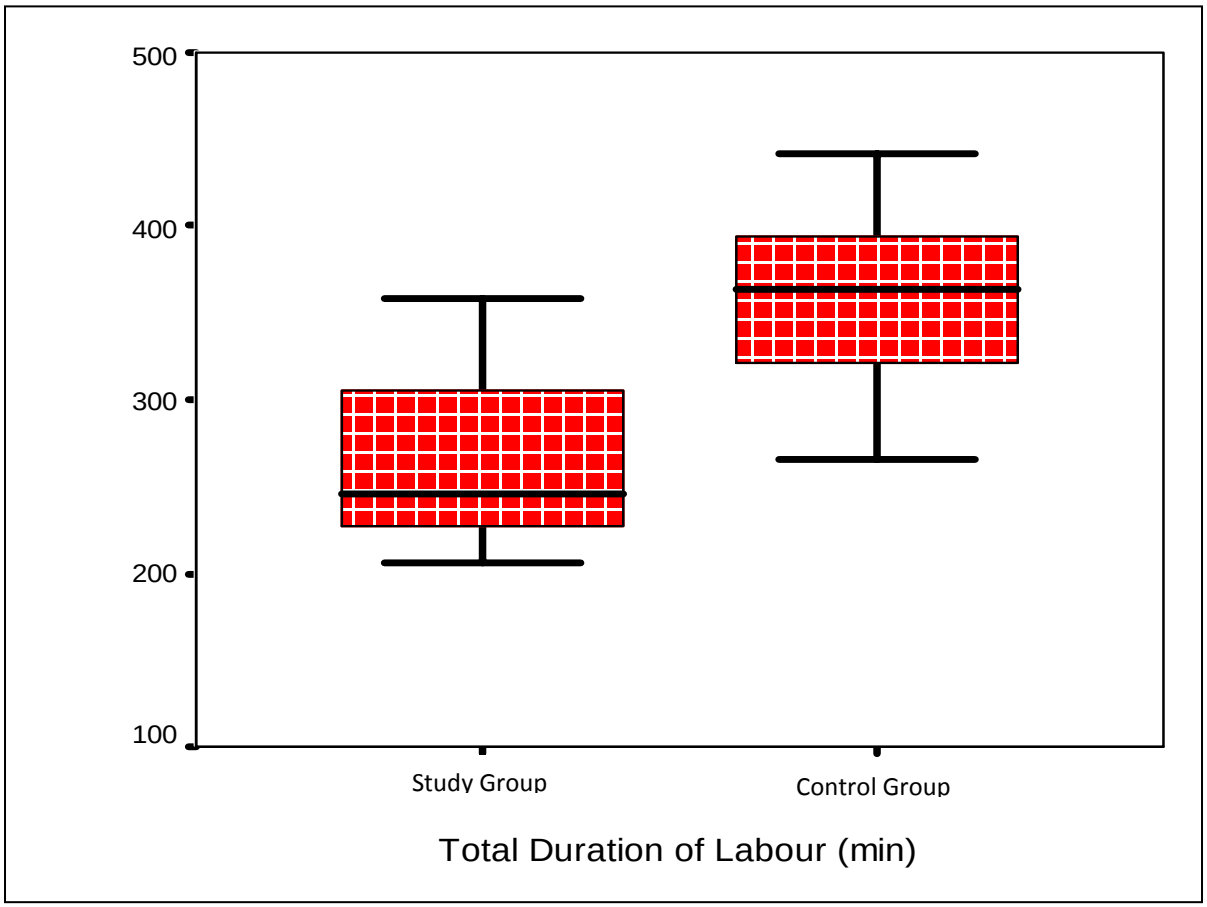
Duration of Labour [Second Stage of Labour (min)]



Duration of Labour [Third Stage of Labour (min)]



Duration of Labour [Total Duration of Labour (min)]



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 ($p > 0.05$). 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 ($p>0.05$).

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 ($p > 0.05$) between the two groups.

Women who had LSCS were excluded for comparison of complications.

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 7: Mode of Delivery in the Studied Subjects

Mode of Delivery	Study Group		Control Group		p value
	n	%	n	%	
Vaginal	**94**	**94.0**	**92**	**92.0**	0.580 (NS)
LSCS	**6**	**6.0**	**8**	**8.0**	

Table 8: Apgar Score of Babies in the Studied Groups

	Study Group [Mean±SD]	Control Group [Mean±SD]	p value
1 minute	7.7 ± 1.2 (6, 10)	7.8 ± 1.2 (6, 10)	0.636 (NS)
5 minute	9.6 ± 0.8 (8, 10)	9.7 ± 0.7 (8, 10)	0.204 (NS)

Table 9: Birth Weight (Kg) of Neonates in the Studied Groups

Group	Birth Weight (Kg) [Mean±SD]	p value
Study Group	2.9 ± 0.2 (2.3 ,3.4)	0.123 (NS)
Control Group	2.8 ± 0.2 (2.3 ,3.3)	

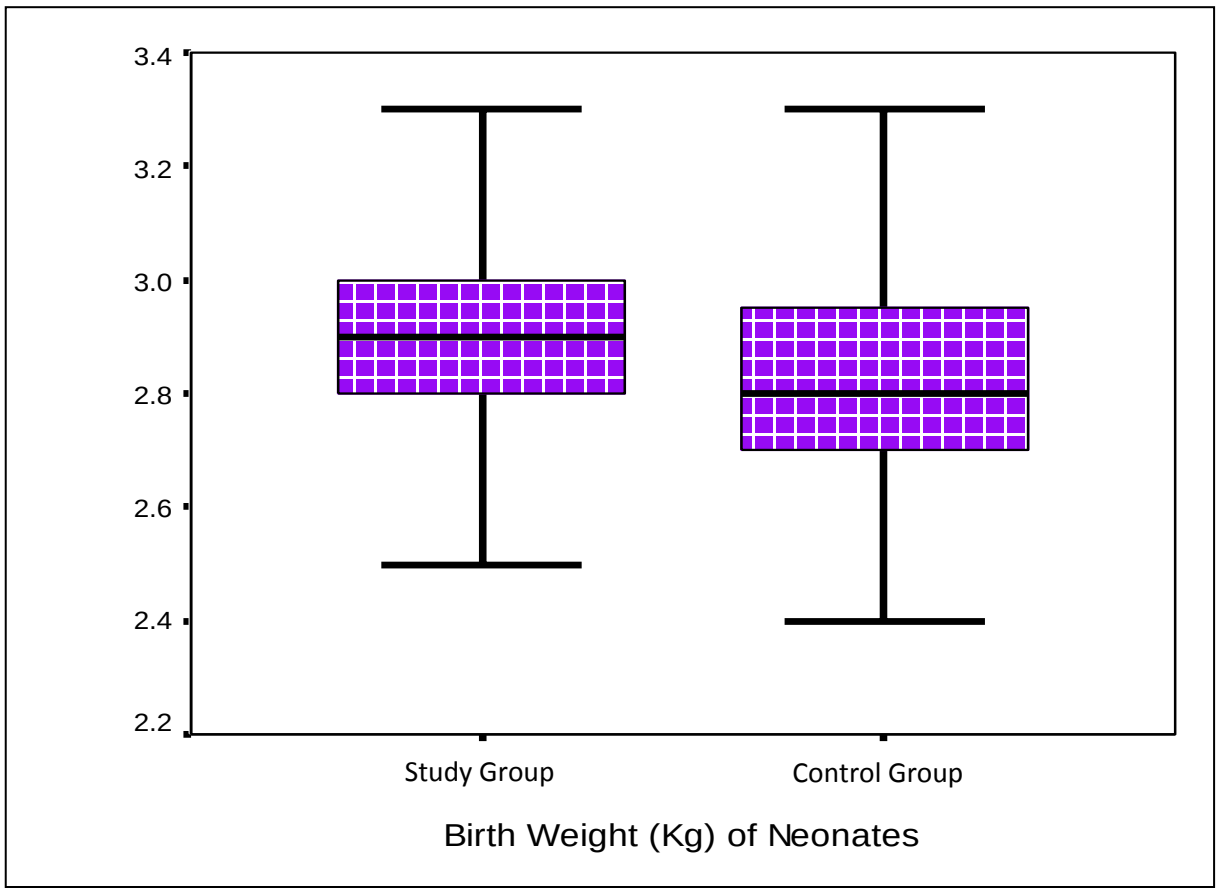


Table 10: Comparison of Maternal Side Effects / Complications in the Studied Subjects

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

Labour is a physiological but painful event. Adequate analgesia during labour is a benefit for the mother, has a positive influence on the course of labour and the state of newborn child.

The use of techniques and medications to provide relief in labour 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. In obstetric analgesia 100mg of Tramadol hydrochloride administered intramuscularly has an analgesic effect equivalent to that of 100mg pethidine or 10mg Morphine administered intramuscularly.[8]

In the present study, efficacy and safety of Tramadol hydrochloride as an analgesic during labour was studied. The patients included in this study were divided into 2 groups- the study group and the control group. The study group consisted of 100 primigravidae who were given injection Tramadol hydrochloride 100mg (2ml) intramuscularly while the control group consisted of 100 primigravidae who received 2ml of placebo (distilled water) at the onset of active labour. The patients in the present study were comparable in terms of demographic data.

Age

In our study, the mean age of the women in the study group was 26±2.8 years and in the control group was 26.1±2.6 years. The difference was statistically insignificant between the two groups.

In the study conducted by Nagaria et al.[9] on 200 primigravidae, the mean age of the women was 23.15±3.94 years in the study group and 22.94±3.37 years in the control group. Similarly Doshi et al.[10] in their study of 100 women reported that the mean age of the women in the study group was 25.5±2 years and was 25±2.5 years in the control group.

In the study conducted by Kuti et al.[11] on 100 women, the mean age of women in the Tramadol group was 30.4 years and in the Pentazocine group was 29.7 years. Thus, the mean age in our study is comparable with other studies.

Gestational Age

Gestational age in majority of women in both the study and control group was 39 weeks and 40 weeks. 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. This was consistent with the study conducted by Nagaria et al.[9] who reported the mean gestational age in the study group as 39.06±1.35 weeks and in the control group as 39.17±1.19 weeks. The mean gestational age in the study conducted by Kuti et al.[11] was 39.5 weeks in the Pentazocine group and 39.3 weeks in the Tramadol group.

Effectiveness of Analgesia and Degree of Pain Relief

In the present study, 31% patients in the study group had horrible pain (Grade 4), 66% had distressing pain (Grade 3) and 3% had discomfort (Grade 2) at the point of entry into study. In the control group, 16% patients had horrible pain (Grade 4), 78% patients had distressing pain (Grade 3) and 6% had discomfort (Grade 2) at the point of entry into study. The difference was statistically insignificant.

Pain intensity using McGills Scale in the study group after 1 hour of drug administration was Grade 4 in 4%, Grade 3 in 29%, Grade 2 in 57% and Grade 1 in 10% women. After 3 hours of drug administration pain intensity in the study group was Grade4 in 0%, Grade 3 in 26%, Grade 2 in 41% and Grade 1 in 33% women. Pain intensity in the control group after 1 hour of drug administration was Grade 4 in 30%, Grade 3 in 60%, Grade 2 in 8% and Grade 1 in 2% women. After 3 hours, pain intensity in the control group was Grade 4 in 51%, Grade 3 in 35%, Grade 2 in 7% and Grade 1 in 7%. The difference was statistically significant between the two groups.

As the labour progresses, the intensity of pain also increases. In our study the percentage of women in the control group who had Grade 4 (Horrible) pain at the time of enrolment in study was 16% which got increased to 30% after 1 hour and to 51% after 3 hours of drug administration where as in the study group the percentage of women who had Grade 4 (Horrible) pain at the time of enrolment in study was31% which got decreased to 4% after 1 hour and to 0% after 3 hours of drug administration. The percentage of women in the study group who had Grade3 (distressing) pain at the time of enrolment in the study was 66% which got decreased to 29% after 1 hour and to26% after 3 hours of drug administration indicating that Tramadol hydrochloride has very good efficacy as an analgesic in labour and it decreases the intensity of pain.

In the study conducted by Doshi et al.[10], 70% women had Grade 2 (Discomfort) pain and30% had Grade3 (Distressing) pain in the Tramadol group as compared to Grade1(mild) pain in 6%, Grade2 (Discomfort) in 20%, Grade3 (Distressing) in 48% and Grade 4 (Horrible) in 24% in the control group using McGills pain intensity scale.

In the present study, Pain relief using Oxford Score in the study group after 1 hour of drug administration was moderate (Grade 3) in 19%, Slight (Grade 2) in 45% and none (Grade 1) in 36% women. After 3 hours of drug administration, 7% women had good (Grade 4) relief of pain, 33% had moderate (Grade 3) relief of pain, 35% had slight (Grade 2) relief of pain and 25% had no relief (Grade1) of pain. In the control group, after 1 hour of drug administration, 36% women had slight (Grade 2) relief of pain and 64% had no (Grade 1) relief of pain using Oxford pain relief score. After 3 hours of drug administration 23% women had slight (Grade 2) relief of pain and 77% had no (Grade 1) relief of pain.

This was consistent with the study conducted by Doshi et al.[10] where 28% of women had no (Grade 1) pain relief, 40% had slight (Grade 2) and 32% had moderate (Grade 3) relief of pain at 3 hours of drug administration in the study group using oxford pain relief score.

In the study conducted by Nagaria et al.[9] 9% of women had no relief of pain, 16% had mild relief of pain, 38% had moderate relief of pain and 37% had good relief of pain in the study group.

Similarly Bajaj et al.[12] in their study reported that 20% of women had no relief of pain, 33% had mild relief of pain, 38% had moderate relief of pain and 9% had good relief of pain in the study group.

Thus the pain relief in our study is consistent with the studies by Doshi et al.[10], Nagaria et al.[9] and Bajaj et al.[12]

Duration of Labour

In the present study, 6 women in the study group and 8 women in the control group had to undergo LSCS and were thus excluded for comparison of the duration of labour. The mean duration of the active phase of first stage, second stage and third stage in the study group was 222.2±40.9 minutes, 33.2±6.8 minutes and 5.1±1.3 minutes respectively. The mean duration of active phase of first stage, second stage and third stage of labour in the control group was 308.7±37.7 minutes, 42.3±9.2 minutes and 8.7±2.9 minutes. The difference in the mean duration of first, second and third stages of labour between the two groups was statistically significant ($p < 0.05$).

The total duration of labour from enrolment in the study till delivery was 260.5±41.3 minutes in the study group and 359.7±44.3 minutes in the control group. The difference is statistically significant ($p < 0.05$) between the two groups.

In the study conducted by Meena et al.[13] the mean duration of active phase of first stage, second stage and third stage of labour in cases was 3.40±1.55 hours, 17.46±5.06 minutes and 4.94±1.43 minutes respectively. In the control group, the mean duration of active phase of first stage, second stage and third stage of labour was 4.50±1.20 hours, 31.6±5.96 minutes and 7.66±2.66 minutes respectively.

In the study conducted by Nagaria et al,[9] the duration of first, second and third stage of labour in the Tramadol group was 4.28±2.22 hours, 0.30±0.05 hours and 0.04±0.01 hours respectively. In the Pentazocine group, the duration of first, second and third stage was 5.16±2.47 hours, 0.42±0.58 hours and 0.04±0.0015 hours respectively.

Injection Delivery Interval

In the present study, the mean 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 was statistically significant ($p < 0.05$) between the two groups.

Kuti et al.[11] in their study recorded injection delivery interval in the Tramadol group to be 213.7 minutes and in the Pentazocine group to be 256.2 minutes. where as in the study of Nagaria et al.[9] Injection delivery interval was 3.17±2.05 hours in the study group and 4.21±2.62 hours in the control group.

Thus the mean injection delivery interval in our study is consistent with studies by Nagaria et al.[9] and Kuti et al.[11].

Mode of Delivery

In the present study, 94% women in the study group and 92% women in the control group had spontaneous vaginal delivery. 6% women in the study group and 8% women in the control group had to undergo lower segment caesarean section. The difference in the mode of delivery between the two groups was statistically insignificant.

In the study by Doshi et al.[10] on 100 women, 92% women in both the study group and in the control groups delivered normally vaginally, 4% in the study group and 6% in the control group needed instrumental delivery and 4% in the study group and 2% in the control group needed caesarean section.

Similarly Nagaria et al.[9] in their study on 200 women reported normal vaginal delivery in 93% women in the study group and 90% women in the control group. 4% women in the study group and 8% women in the control group needed forceps application and 3% women in the study group and 2% women in control group had to undergo caesarean section.

Thus, the mode of delivery in the study and the control groups of these studies indicate that there is no increase in operative delivery rate when Tramadol hydrochloride was used as analgesic.

Neonatal Outcome

The neonatal outcome was assessed by studying the Apgar score at 1 and 5 minutes after birth. The mean Apgar score of babies in the study group at 1 and 5 minutes was 7.7±1.2 and 9.6±0.8 respectively. The mean Apgar score of babies in the control group at 1 and 5 minutes was 7.8±1.2 and 9.7±0.7 respectively. The difference was statistically insignificant between the two groups. All the babies in the study and control groups had Apgar score between 8-10 at 5 minutes. There was no still birth or neonatal death in both the groups.

Similar results were reported in the study conducted by Thakur et al.[14], where the mean Apgar score in the study group was 7.02±0.06 at 1 minute and 9.05±0.88 at 5 minutes while Nagaria et al.[9] in their study reported Apgar score >7 in 98% babies in the study group and 90% babies in the control group at 1 minutes.

Birth Weight

The mean birth weight of the neonates in the study group observed was 2.9±0.2kg and in the control group was 2.8±0.2kg. The difference was statistically insignificant.

Side Effects and Complications

In the present study, minor side effects like nausea, vomiting were seen in women in both the study and control group. The difference was statistically insignificant between the two groups. No major complications were 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. These were comparable to those reported by Doshi et al.[10] where minor complications like nausea, vomiting and dizziness were seen in both the study and control groups and the difference was statistically insignificant between the two groups.

CONCLUSION

The study group had a significant decrease in pain intensity after single dose (100mg) of injection Tramadol hydrochloride administration as compared to control group. 75% women in the study group had substantial relief of pain with statistically significant reduction in duration of first, second and third stages of labour. The total duration of labour was significantly less in the study group as compared to that in the control group. There was

no increase in the operative delivery rate and no adverse effect on neonatal outcome. There was no change in fetal heart rate; there were no still births or neonatal death in the study group. The maternal morbidity was much less. Nausea and vomiting were only side effects observed after administration of Tramadol hydrochloride. Thus the study conclude that Tramadol hydrochloride given intramuscularly in active labour offers good labour analgesia without any adverse effects on maternal and fetal vital parameters.

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