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Usefulness of tramadol as an analgesic during labour: A clinical study at a tertiary care hospital

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Abstract
Pain is a sensory experience that is subjective and an individual experience. Labour pain if not adequately controlled can lead to maternal and fetal sequelae because of widespread maternal sympathetic activation that causes increase in cardiac output, blood pressure and pulse rate of the mother. Providing effective and safe analgesia during labour has remained an ongoing challenge. A good analgesic will provide safe and effective analgesia in labour with minimal maternal and fetal side effects. Patients satisfying the inclusion /exclusion criteria, 35 in each arm, were taken into the study after taking informed consent. All patients were interviewed with a structured questionnaire to elicit presenting complaints, obstetric history, past medical and surgical history. The first participant included in the study group was selected randomly and thereafter alternate participants were included in the interventional group. In the intervention group, the mean VAS score before the drug administration, in the first stage of labour was 7.54 with a standard deviation (SD) of 1.597, while in the control group the mean Vas score was 6.58 with SD of 0.998.In the intervention group, the mean VAS score after the drug administration in the first stage of labour was 3.76 with SD of 1.611, while in the control group the mean Vas score remained at 6.58 with SD of 0.998. The student t test was used to compare the data across the groups, t=8.739, and p=.000, p-value <0.001 → is found to be statistically significant.

Keywords: Tramadol, analgesic during labour, VAS

Introduction
Labour is a painful event for majority of women, may be the most painful event that she has ever experienced [1]. It is unpleasant, disturbing and extremely unbearable for many. "The delivery of a healthy baby into the arms of a conscious and pain-free mother is one of the most exciting and rewarding moments in medicine".

In former years progress of labour was assessed by degree of pain experienced by mother, and that labour pain was thought to be an indication of a successful labour outcome. This led to negligence of labour pains. To add to the misery, pain relief was denied to the women in labour on the basis of religious, cultural and social grounds.

It was in 1846, that first time labour analgesia was provided by Simpson by administering ether and delivered a dead child, which led to wide spread opposition from the laymen, public and clergy group. But won the support of the lay public in 1853, when Sir John Snow anesthetized Queen Victoria for the birth of the 8th child, prince Leopald. Spinal anaesthesia was introduced by Bier 1899, and by 1907, it was used almost in all branches of surgery including obstetrics and gynecology. Subarachnoid block, caudal block for vaginal delivery and scopolamine and morphine for 'twilight sleep' during labour were introduced during first 2 years of 19th century. The value and safety of Nitrous oxide/oxygen or air mixtures were known, but early apparatus was cumbersome [2, 3].

It was not until 1933, when Minnitt introduced a portable Nitrous oxide/air machine that inhalation analgesia became widespread. Unfortunately, the mixture of Nitrous oxide and air was hypoxic. Nevertheless, the Minnitt apparatus was used widely in UK for many years [2, 3]. By trial and error, the pioneers in obstetric analgesia have finally proved that if performed with adequate care and skill, following are the features of an ideal analgesic:

- It should be safe.
- It should provide good analgesia.
- It should not cause maternal and fetal depression.
- It should not affect progress of labor.

- It should not have unpleasant side effects.
- It should have high technical success rate.

This study tests if tramadol hydrochloride fulfils the features of an ideal analgesic for labour [4].

Pain is a sensory experience that is subjective and an individual experience. Labour pain if not adequately controlled can lead to maternal and fetal sequelae because of widespread maternal sympathetic activation that causes increase in cardiac output, blood pressure and pulse rate of the mother. Providing effective and safe analgesia during labour has remained an ongoing challenge. A good analgesic will provide safe and effective analgesia in labour with minimal maternal and fetal side effects.

In this study, the merits, demerits and outcome of intramuscular (IM) tramadol as labour analgesia and the effect of the drug in both mother and baby will be evaluated.

Methodology

All patients with Term pregnancy (gestational age between 37-42wks) without cephalopelvic disproportion, in active labour, admitted to the Labour Room of Medical College and Research Foundation. Patients satisfying the inclusion /exclusion criteria, 35 in each arm, were taken into the study after taking informed consent. All patients were interviewed with a structured questionnaire to elicit presenting complaints, obstetric history, past medical and surgical history. The first participant included in the study group was selected randomly and thereafter alternate participants were included in the interventional group. All patients were examined and assessed routinely for vital parameters like pulse rate, blood pressure, respiratory rate, Hb%, Blood group and Rh typing, urine analysis for albumin, sugar, microscopy.

Prior to the start of the technique, proper assessment of the patient was done with special reference to obstetric history. All narcotic analgesic drugs were withheld for these patients who were subjected to the study, in order to avoid drug interaction.

Active Phase of labour is defined as cervical dilatation of ≥3cm with ≥80% effacement, with good uterine contraction of at least 2-3 contractions every 10 minutes lasting for ≥40 seconds. Group-I (study group). Once the patient is in established active phase of labour i.e., ≥ 3cm dilatation, ≥80% effacement, with good uterine contraction, vital signs, foetal heart rate were recorded, and pain score noted before administering the drug. Intensity of pain was assessed using Visual Analog Scale (VAS).

Injection tramadol 100mg IM was given. Pulse rate, respiratory rate, blood pressure, foetal heart rate were recorded.

The following observations were recorded

1. Vital parameters were checked initially every 10 minutes for the first 30 minutes, then at 15 minutes interval for next 1hr and later on, every 30 minutes were monitored.
2. VAS score was noted after 30 min. of drug induction.
3. Any side effects of the drug were noted.
4. Foetal heart rate monitoring was done clinically and any variability was noted.
5. Progress of labour was monitored using a partogram.
6. The duration of labour, the degree of pain relief, the mode of delivery and recovery time in each patient were noted and recorded.
7. Apgar score at 1 and 5 minutes were recorded.
8. Any complications during the course of labour were recorded. Patients were observed for 2 hours after delivery and were shifted to the ward if there was no complication.

Group-2 (Control group) – 35 patients were selected of the same age group, parity and socioeconomic status. The patients were observed in the same manner as the study group.

Assessment of Pain Relief

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

By the patient: Because the perception of pain relief is subjective, this variable was standardized using data from VAS (visual analogue scale) in the study participants.

VAS

A 10cm line is drawn on a piece of white paper and represents the patient's opinion of the degree of pain. It was explained to the subject that one end of the line represents as much pain as she can possibly imagine, while the other represents no pain at all. The subject rates the degree of pain by making a mark on the linear scale. Values are obtained by measuring the distance from 0 to that mark.

Results

Table 1: Mode of Delivery

Mode of Delivery	Intervention Group	Control Group
FTND with RMLE	33	31
FTND	0	2
FT Vacuum Delivery	1	0
LSCS	1	2

Fishers exact test =3.396 and p= 0.335; p>0.05 statistically not significant

In the Intervention group 94% (33) patients had normal vaginal delivery all of which were FTND with episiotomy (RMLE). In the control group also, 94% patients (33) had normal vaginal deliveries of which 5.71% (2 patients) had FTND and 88.57% (31 patients) had FTND with episiotomy. In the Intervention group 2.85% (1 patient) underwent LSCS, indication was fetal distress with thin meconium stained liquor.2.85% (1patient) had a Vacuum delivery indication being prolonged second stage with failure of secondary forces/powers.

In the control group 5.7% (2 patients) were taken for caesarean section due to fetal distress. Fishers exact test =3.396 and p= 0.335; Not significant.

Table 2: VAS Score

Mean VAS Score	Intervention Group	Control group
Before Drug Induction in First Stage	7.54± 1.597	6.58 ±0.998
After Drug Induction in First Stage	3.76 ±1.611	6.58 ±0.998
Second Stage	4.85 ±1.861	8.18 ±1.103

In the intervention group, the mean VAS score before the drug administration, in the first stage of labour was 7.54 with a standard deviation (SD) of 1.597, while in the control group the mean Vas score was 6.58 with SD of 0.998.

In the intervention group, the mean VAS score after the drug administration in the first stage of labour was 3.76 with SD of 1.611, while in the control group the mean Vas score remained at 6.58 with SD of 0.998. The student t test was used to compare the data across the groups, t=8.739, and p=.000, p-value <0.001 → is found to be statistically significant.

In the intervention group, the mean VAS score after the drug administration in the second stage of labour was 4.85 with a SD of 1.861, while in the control group the mean Vas score was at 8.18 with a SD of 1.103.

The student t test was used to compare the data across the groups, t=8.874, and p=.000, p-value <0.001 → statistically significant.

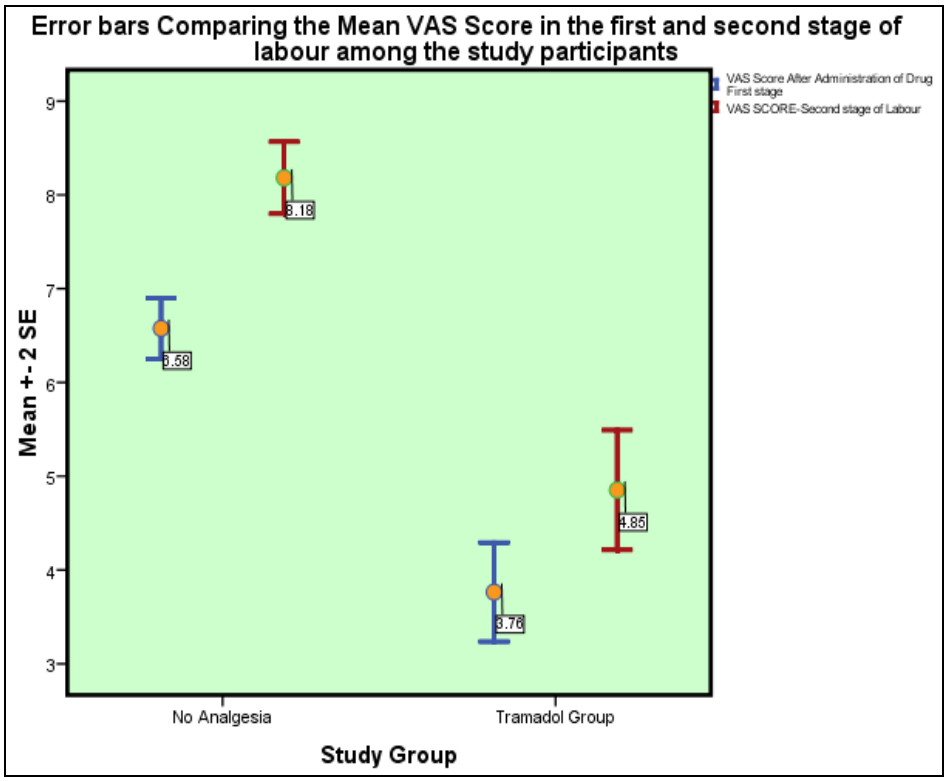

Fig 1: Error bars depicting the mean VAS score in first and second stage of Labour in the Intervention and Control (no analgesia) groups.

The mean VAS score in the first stage of labour in the control group was 6.58±2SE (standard error) whereas in the intervention group after Tramadol administration it was 3.76±2SE, and is statistically significant. In the second stage of labour the mean VAS score in control and Tramadol groups were 8.18±2SE and 4.85±2SE respectively, statistically significant.

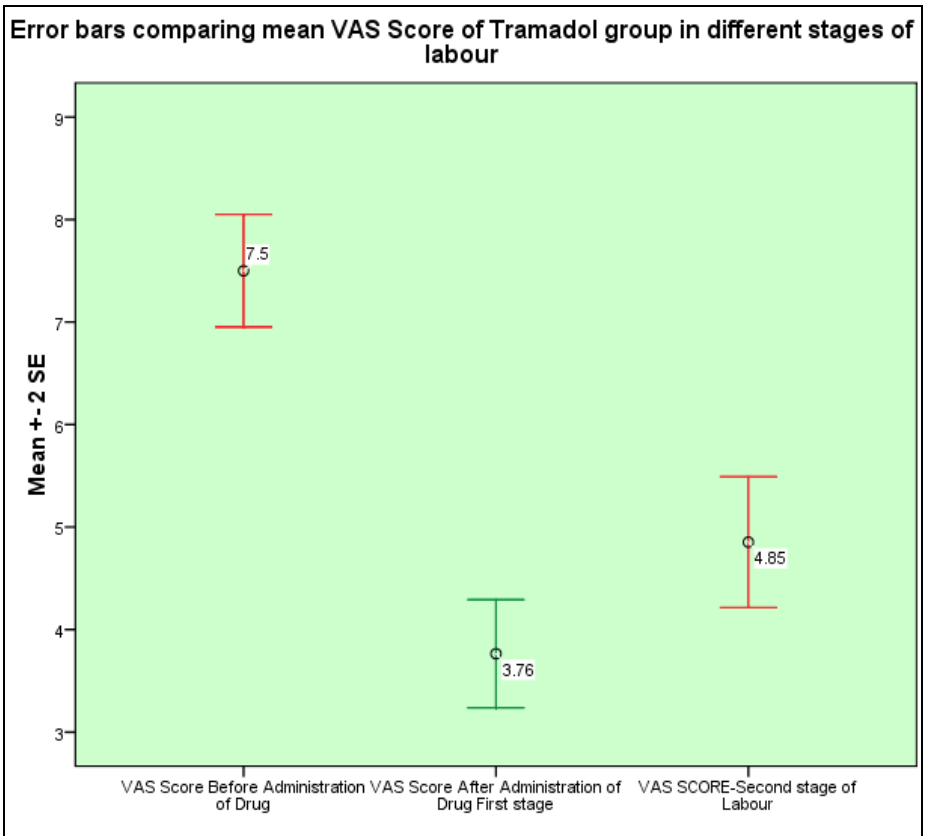

Fig 2: Error Bar depicting the mean VAS scores, +/- 2SE (95% confidence levels) in the Intervention group before drug induction in first stage, after induction in first stage of labour and in second stage of labour.

In the intervention group the mean VAS scores were 7.54 ±2 SE before tramadol administration, 3.76 ±2SE after tramadol administration in the first stage and 4.85 ±1.2SE in the second stage of labour. Hence, it can be proved with 95% confidence that pain has significantly reduced in intensity with the administration of tramadol. Patients were found to be very co-operative at the time of suturing of episiotomy wound in the intervention group compared to control group.

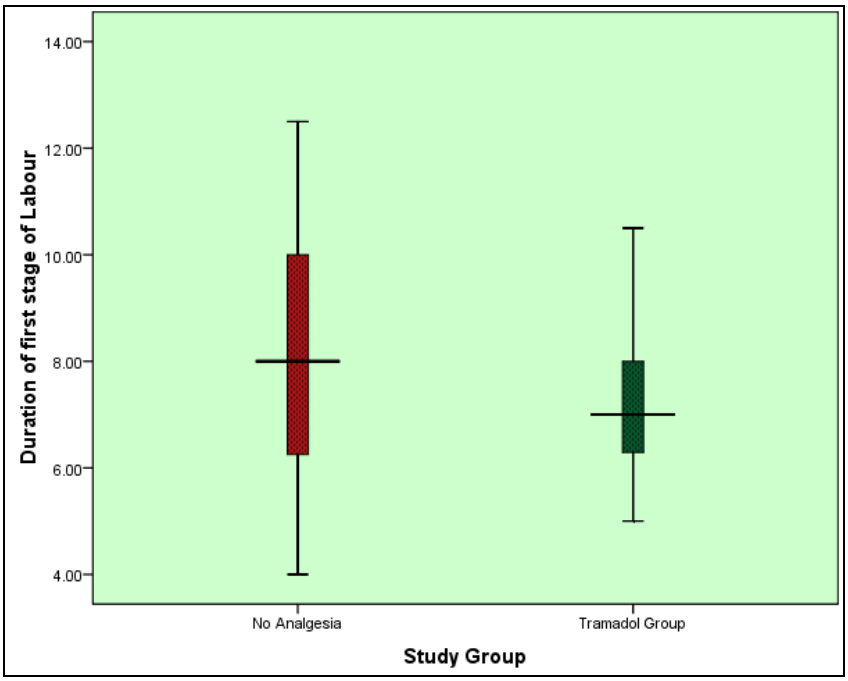

Fig 3: Box Plot comparing the duration of first stage of labour among the intervention and control groups.

In the intervention group, the duration of first stage of labour ranged from 5.0-9.5 hours with a mean value of 7.31 ± 1.26hrs while the duration of first stage labour in the control group ranged from 5.0-12.5 hours with mean value of 8.18 ±2.1hrs. p= 0.046. p-value <0.05 → is statistically significant.

The reduction in duration of first stage of labour as observed here was 0.87hrs (52.2 min.) and this reduction in duration is statistically significant.

Table 3: Duration of labour among the Intervention and control groups

Mean Duration of Labour	Intervention Group	Control Group	P value
I stage (in hrs)	7.31±1.26	8.18±2.1	0.046
II stage (in min)	40.14±15	35.29±15.2	0.184
III stage (in min)	8.40±3.9	8.6±4.7	0.956

Table-3 shows the duration in different stages of labour in intervention and control groups. In the intervention group, the duration of II stage labour ranged from 16-75 min with a mean value of 40.14 ±15 min. while in the control group it ranged from 15-60 min with mean value of 35.29 ±15.2min. p=0.184, is statistically not significant. In the intervention group, the duration of III stage labour ranged from 5-15min with a mean value of 8.40±3.9min. while in the control group it ranged from 3-20min with mean value of 8.6±4.7min. p=0.956, is statistically not significant.

Table 4 shows the Drug induction Delivery time. In the Intervention group the mean drug induction delivery time i.e. the time interval between the drug induction and time of delivery was found to be 3.46hhrs with SD of± 0.98hrs (59min).

Table 4: Drug Induction Delivery time

Group	Mean (in hrs)	Std. Deviation (in min)
Intervention	3.46	59.461

Discussion

In this present study, the effect of intramuscular tramadol, when given to women in labour, in the age group of 18-35 years was studied. Primigravidae & multigravidae were taken into consideration in both study and control groups. They belonged to the same socioeconomic status. The study participants were 70 women, with 35 in each arm (Intervention & control group).

Pain is a subjective phenomenon and so its relief is difficult to measure. As pain is subjective and totally an individual experience, in the present study, this variable was standardized by using data from Visual Analogue Scale (VAS).

The different modes of delivery among the intervention groups in the study conducted by Nagaria T, Acharya J, Usha RS and the present study

In the present study 94% patients had full term normal delivery in both the study and control group, while in the study conducted by Nagaria T, Acharya J, [5] 93% had full term normal delivery. In the study conducted by Usha RS *et al*, [6] 84% had full term normal delivery.

In the present study, 2.85% (1 patient) of the intervention group underwent LSCS, the indication being, fetal distress with thin meconium stained liquor. Intraaoperative findings were → 1 loop of tight cord around the baby's neck, thin meconium stained liquor. In the study conducted by Nagaria T, Acharya J, [5] 3% of them were delivered by LSCS. In the present study, among the control group, 5.7% (2 patients) delivered by LSCS, the indication being fetal distress. One of them had thin meconium stained liquor on ARM (artificial rupture of membranes). Intraoperatively both the babies had a loop of nuchal cord. But in the study conducted by Usha RS *et al*. [6] 6% of patients in study group and 14% of patients in control group underwent caesarean section. In the present study, 2.85% (1 patient) among the intervention group delivered by instrumental delivery. It was a Vacuum delivery, the indication being prolonged second stage of labour with failure of secondary

forces/powers. There were no instrumental deliveries in the control group. In the study conducted by Usha RS *et al.* [6], 10% patients among the study group and 20% among the control group delivered by forceps delivery. Nagaria T, Acharya J reported forceps delivery in 4% & 8% among study and control groups respectively. This wide variation in the modes of delivery in the present study when compared to the studies conducted by Usha RS *et al.* [6]; Nagaria T, Acharya J [5] cannot be attributed to the administration of Tramadol due to the smaller sample size(35 in each arm) included in the present study. However administration of tramadol to participants in the intervention group has not resulted in excessive instrumental deliveries or Caesarean sections. A further study with a larger sample size is needed to explain the effect of tramadol on the mode of delivery. In the present study, the duration of first stage of labour among the intervention group ranged from 5.0-9.5 hours with a mean 7.31 ± 1.26hrs while the duration of first stage labour in the control group ranged from 5.0-12.5 hours with a mean value of 8.18 ±2.1 hrs. The reduction in the duration of first stage of labour as observed here was 0.87hrs (52.2 min.) p= 0.046; and this is statistically significant.

In a study conducted by Nagaria T, Acharya J, [5] the mean duration of first stage of labour (4.28± 2.22hrs.) in the study group was shorter compared to the control group (5.16 ±2.47hrs.) which supports the findings of the present study. In a study conducted by Thakur R, Patidar R, [7] the mean duration of first stage of labour in the tramadol group was 4.26 ± 1.62 hrs while in the control group it was 4.50 ± 1.46 hrs. P-value >0.05, statistically not significant.

Meena J *et al.* [8] reported the mean duration of first stage of labour was 5hrs.45min in the study group, while in the control group it was 8hrs 39 min, p-value <0.05 → is statistically significant. The mean duration of the first stage of labour among the intervention and control groups in the studies conducted by Nagaria T, Acharya J [5]; Thakur R, Patidar R [7]; Meena J *et al.* [8] and the present study. In the present study among the intervention group, the duration of second stage of labour ranged from 16-75 min with a mean value of 40.14 ±15 min while the duration of second stage of labour in the control group ranged from 15-60 min with mean value of 35.29 ±15.2min. p=0.184, with p-value >0.05 → is statistically not significant. In a study conducted by Nagaria T, Acharya J[5] there was no statistically significant difference in the duration of second stage labour among intervention and control group, thus supporting this study. Daftary *et al.* [9] reported the mean duration of second stage of labour to be 26 min. In a study conducted by Thakur R, Patidar R [7] mean duration of second stage of labour in the tramadol group was 11.95 ± 5.8min, in the control group it was 14.65 ± 10.9 min, with p-value >0.05 → is statistically not significant, similar to the present study.

The mean duration of the second stage of labour (minutes) among the intervention and control groups in studies conducted by Nagaria T, Acharya J [5]; Thakur R, Patidar R [7] and the present study.

In the present study, among the intervention group the duration of third stage of labour, ranged from 5-15min with a mean value of 8.40 ±3.9min while in the control group it ranged from 3-20min with mean value of 8.6 ±4.7min. p=0.956, with p-value >0.05 → is statistically not significant.

Sudha P *et al.* [10] reported the mean duration of third stage of labour to be 6 min. among the study participants. A study by Nagaria T, Acharya J [5] reported the mean duration of third stage of labour as 4±1.5minutes. Daftary [9]; Meena J *et al.* [8] reported as 4.6 minutes, & 4.94 minutes respectively which are comparable to the present study. In a study conducted by Usha RS [6] *et al.* there was significant shorter duration of labour in study group compared to control group which supports the present study.

In the Intervention group the mean drug induction delivery time i.e. the time interval between the drug induction and time of delivery was found to be 3.46 ± 0.98hrs (59min). In a study conducted by Nagaria T, Acharya J [5], the mean drug induction delivery time was 3.17±2.05hrs comparable to the present study.

Labour pain is among the most severe pain experienced by women. Pregnant women are entitled to have basic information about pain and its relief. Since ages, obstetricians have been looking for helping these labouring women. Providing effective and safe analgesia during labour has remained an ongoing challenge. Concern for maternal and foetal safety and desire for a satisfactory birth experience have fostered an anti-anaesthesia atmosphere and has led obstetricians to resort to alternate methods of pain relief e.g., hypnosis, Psychoprophylaxis. Tramadol a pharmacological method has centrally acting analgesic action by opiod and non opiod mechanism [7].

In the intervention group, the mean VAS score before the drug administration in the first stage of labour was 7.54 ± 1.597, while in the control group it was 6.58 ± 0.998. In the intervention group, the mean VAS score after the drug administration in the first stage of labour was 3.76 ±1.611, while in the control group the mean Vas score remained at 6.58 ± 0.998. The student t test was used to compare the data across the groups, t = 8.739, and p =.000, p-value <0.001, is found to be statistically significant.

Thus the administration of tramadol significantly reduced the intensity of pain in the first stage of labour in the intervention group when compared to the control group. In a study conducted by Thakur R, Patidar R, [7] 86% of the participants in the study group (after administration of tramadol) had pain relief with complete relief in 15%, moderate relief in 55% and mild relief in 16% of the study group.14% of the study group had no relief. Nagaria T, Acharya J [5] reported 37% with satisfactory relief, 38% with moderate relief, 16% with mild relief and no relief in 9% in Tramadol group. In a study conducted by Sudha P *et al*, [10] among the participants in the study group 58% had good relief, 30% moderate relief and 12% had mild relief in pain after tramadol administration. In the present study, among the intervention group, the mean VAS score after the drug administration in the second stage of labour was 4.85 ±1.861, while in the control group it was at 8.18 ±1.103.The student t test was used to compare the data across the groups, t=8.874, and p=.000 → statistically significant

the degree of pain relief following tramadol administration in the tramadol group according to studies conducted by Thakur R, Patidar R [7]; Nagaria T, Acharya J [5]; Sudha P *et al.* [10]; Usha RS, Verma RS *et al.* [6] Therefore it can be positively said that Tramadol has decreased the intensity of pain, both in the 1st and 2nd stages of labour. In the present study it is also noteworthy to mention that the study participants were very co-operative at the time of suturing of the episiotomy wound in the intervention group as compared to the control group. This has proven beyond doubt, that tramadol is very useful as an analgesic in labour.

Conclusion

From the present study, it can be concluded that Tramadol hydrochloride is an effective drug which can be used for labour analgesia and which is safe for both the mother and the baby, with minimal side effects. The drug is easily available, low cost; its mode of administration is simple, and practically feasible in

any set up. Maternal side effects are minor without any fetal or neonatal respiratory depression. It provides the expectant mother, with the satisfaction of a normal child birth, by reducing labour pains thereby decreasing the agony of the parturient. The overall duration of labour is also significantly reduced with the use of Tramadol. Hence intramuscular injections of Tramadol Hydrochloride could be considered as a safe and effective analgesic in labour.

References

1. Kainz C, Joura E, Obwegeser R, Plockinger B, Gruber W. Effectiveness and tolerance of tramadol with and without an antemetic and pithidine in obstetric analgesia. Geburtshilfe perinatal. 1992; 196:78-82.
2. Lee CR, McTavish D, Sorkin EM. Tramadol: a preliminary review of its pharmacodynamic and pharmacokinetic properties and therapeutic potential in acute and chronic pain status. Drugs. 1993; 46:313-340.
3. Viegas OA, Khaw B, Ratnam SS. Tramadol in labour pain in primi parous patient. A prospective comparative trial. Eur J Obstet Gynecol Reprod Biol. 1993; 49:131-5.
4. Lehman KA. Tramadol for the management of acute pain. Drugs. 1994; 47(1):19-32.
5. Nagaria T, Acharya J. Pain relief in labour tramadol versus pentazocine. J Obstet Gynecol India. 2006; 56(5):406-409.
6. Usha RS, Verma RS. Use of Tramadol as Analgesic in normal and abnormal labour. J Obstet Gynecol India. 1999; 49(6):67-69.
7. Thakur R, Patidar R. Comparative study of transcutaneous electric nerve stimulation and Tramadol Hydrochloride for pain relief in labour. J Obstet Gynecol Ind. 2004; 54(4):346-350.
8. Meena J, Singhal P, Choudhary D. J Obstet Gynaecol India. 2006; 56:53-55.
9. Daftary SN, Desai SV, Nanavati MS *et al*. Programmed Labour- an indigenously developed protocol of labour management. Int. J Gynaecol Obstet. 2003; 6:47-9.
10. Sudha P, Somashekara SC, Veerabhadra Goud GK. Tramadol in Labour. Int. J Pharm Biomed Res. 2012; 3(1):49-51. Available online from www.pharmscidirect.com.