WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 8.453
Volume 13, Issue 22, 997-1007. Research Article ISSN 2277–7105

A PROSPECTIVE STUDY ON GRAVIDITY AND DEFENCE IN WOMEN ARISING FROM THE USE OF TRAMADOL HYDROCHLORIDE AS AN INTRAPARTUM LABOUR ANALGESIC AT TERTIARY CARE TEACHING HOSPITAL

Upendra N.[1], J. S. Venkatesh[2], Nayana Ranju[3]*, Neeraja Sajeev[4], Nikhitha Das C. S.[5], Nithya M. Mathew[6]

[1]Asst. Professor, S. C. S. College of Pharmacy, Harapanahalli.

[2]Professor, S. C. S. College of Pharmacy, Harapanahalli.

[3-6]Pharm D Interns, S. C. S. College of Pharmacy, Harapanahalli.

Article Received on
03 October 2024,

Revised on 23 October 2024,
Accepted on 13 Nov. 2024

DOI: 10.20959/wjpr202422-34605

***Corresponding Author**
Nayana Ranju
Pharm D Interns, S. C. S. College of Pharmacy, Harapanahalli.

ABSTRACT

Background:- Adequate analgesia during labour is beneficial to the mother and has a positive influence on the course of labour and the new born child. There making obstetrical analgesia an essential part of modern obstetrics. Tramadol, opioid used in the treatment of moderate to moderately severe pain. Data was collected from the patients who were admitted in the Obsterics and Gynecology Department. **Objectives:-** The object of the study was to appraise the safety and efficacy of Tramadol hydrochloride used in labour at tertiary care teaching hospital. **Methods:-** This prospective study base was undertaken in chigateri district hospital for a period of six months to analyse the safety and efficacy of tramadol hydrochloride used in labour. The ethical clearance was obtained from institutional ethics committee of S.C.S College of Pharmacy, Harapanahalli. A total of one hundred and fifty eight cases were reviewed and details such as the demographic details, dose, frequency and laboratory parameters during admission was recorded. **Results:-** The overall data of 158 patients were enrolled in the study. Among the study population of 158 patients, it was noted that 42 had mild pain and 39 had discomforting pain and 30 had distressing pain. Nausea and vomiting are the major side effect of tramadol usage in pregnancy. **Conclusion:-** Our study revealed that, it can be concluded that tramadol

hydrochloride is an effective analgesic drug which can be used for labor and which is safe for both the mother and the baby with minimal side effects.

KEYWORDS: Labour, Tramadol hydrochloride, Analgesic, Pain.

INTRODUCTION

Giving birth is a painful process. The pain experienced during labour has various physiological and psychological measurements and its strength can vary from one woman to another. "The delivery of the healthy baby into the arm of a conscious and pain-free mother is one of the most exciting and rewarding moments in medicine". Labour is defined as the spontaneous onset of regular painful uterine contractions associated with effacement and dilation of the cervix and descent of the preventing past, with or without a show or ruptured membranes.

Pain is known as a key part of the physiology of natural child birth and regarding the optimal support, a woman is able to cope with normal labour pain using the endorphins naturally produced in the body in response to pain and other stressors. Labour is the regular uterine contractions that leads to progressive cervical length changes and there uterine contraction can lead to clear physiological changes in oxygen consumption and cardio-pulmonary function. Pain and agony during child birth is acute often unbearable and at time beyond description in the painful labour there is 28% reduction in the uteroplacental blood flow. Effective analgesia prevents the pain induced hyperventilation and hypocapnia which can be severe enough to produce tetany in painful labour. The Labour pain causes apprehension, stress, anxiety and adversely affect both the courses of labour and foetal outcome, if it is not adequately controlled.

There is variety of noxious stimuli that leads to the pain of labour. They give rise to subjective discomfort, as well as objective alternations in cardio respiratory function and autonomic nervous system. Prolonged labour can lead to increased maternal and neonatal mortality and morbidity, maternal age, Induction of labour premature rapture of membrane, early admission to the labour ward. Proper analgesia is important in short term following and surgical intervention which improves maternal and perinatal outcome. The importance of analgesia as a contribution to overall satisfaction of pain management has been recognized increasingly in the last 50 years.

Opioids are most commonly used systemic medication for labour analgesia. Although they do not typically provide complete analgesic effects, they do not allow the parturient woman to better tolerate labour pain. Opioids are powerful pain-reducing drugs which act through binding to their receptors. They efficacy of systemic opioid and the incidence of their side effects appear to be largely dose- dependent rather than drug dependent.

Tramadol hydrochloride is a narcotic drug introduced in 1971 in Germany and in now available throughout the world. Tramadol is a codeine synthetic analogue and a weak opioid agonist. Tramadol opioid is used in the treatment of moderate to moderately severe pain. It inhibits reuptake of nor adrenaline and 5-hydroxytriptamine and thus activates monoaminergic spinal inhibition of pain. Intramuscular tramadol 50-150mg is found to be equal to 50-100mg intramuscular Pethidine and 100mg tramadol is equal to 10mg morphine. Dose of Tramadol is 50-150mg or 1-2mg/kg in 4-6 hours.

Tramadol also has a minor direct action on smooth muscles; hence it is likely to cause cholestasis, urinary retention and constipation. It produces dose dependant mydriasis and antitussive effect. In contrast to morphine it does not produce dependence, tolerance and addition even after long term use.

Appropriate assessment of pain is necessary in order to adequately assess the quality of its management. Clinical assessment of pain refers to the process of describing pain and its effect on function in sufficient detail to assist in diagnosis and to quantify pain to a selected appropriate therapy and to evaluate response to therapy. Pain being a subjective experience is extremely difficult to assess and measurements primarily depends on the verbal response of patients. The commonly used pain assessment tool in adult are the visual analogue scale (VAS) and the verbal rating scale (VRS). Visual analogue scale is a 10cm or 100cm line which originally has no words or numbers attached to it, but was later modified with words and numbers. It is similar to Verbal rating scale. Numeric pain rating scale (an outcome measure) is an unidimensional measure of pain intensity in adults including those with chronic pain. Other forms of pain assessment tools include Wong-Baker faces rating scale which is suitable where communication is a problem such as in elderly patients and children. Mc Gill Questionnaire permits the scaling of multiple dimensions of subjective experiences of the pain.

METHODOLOGY

This prospective study base was undertaken in Chigateri district hospital for a period of six months to analyse the safety and efficacy of Tramadol hydrochloride used in labour. The ethical clearance was obtained from institutional ethics committee of S.C.S College of Pharmacy, Harapanahalli. A total of one hundred and fifty eight cases were reviewed and details such as the demographic details, dose, frequency and laboratory parameters during admission was recorded. A specially designed performa was used for collecting data which includes patient demographics, medication prescribed and doses for each patient. The study was carried out by considering specific inclusion criteria such as all patients under Tramadol therapy, patient who are admitted for more than two days, pregnant and lactating mother, comorbid cases and exclusion criteria such as patient who are treated from out-patient department, patients with missing sufficient data, those undergoing surgery and who are unwilling to the procedures of the study.

RESULT

A total of 150 patients were enrolled in this study to have the fulfilled selection criteria. The length of the stay in the hospital was in the period of more than 2 days. All quantitative variables like age were expressed in variables and percentage.

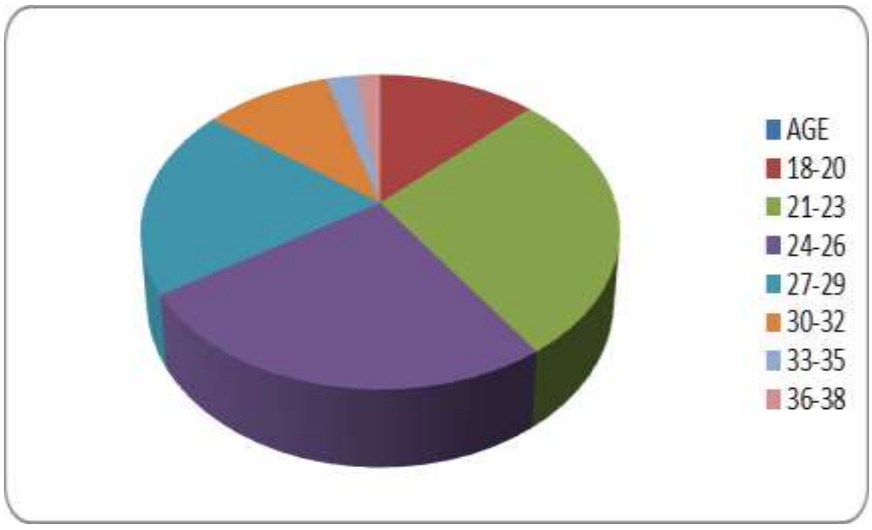

Figure 1: Age -wise distribution of study patients.

The maximum patients were in age group of 21-23(27.8%), (25.3%) in the age group of 24-26, and (19.6%) were in between 27-29. The mean age was 25±21.3.

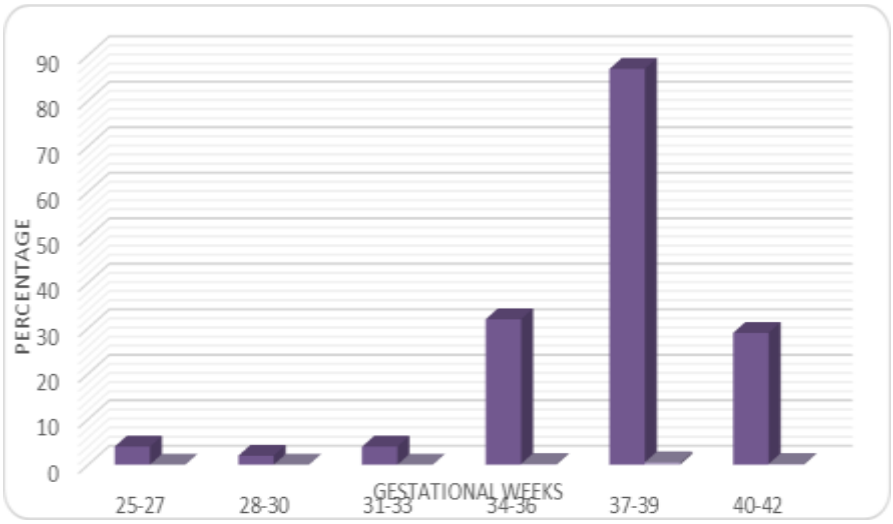

Figure 2: Distribution of subjects according to gestational week.

Among 158 participants, 87 (55%) shown longer gestational week ranges 37-39 and 2 (1.2%) shown 28-30 weeks. The mean gestational period of study subject was 37.3±16.4 and the range was 37-39.

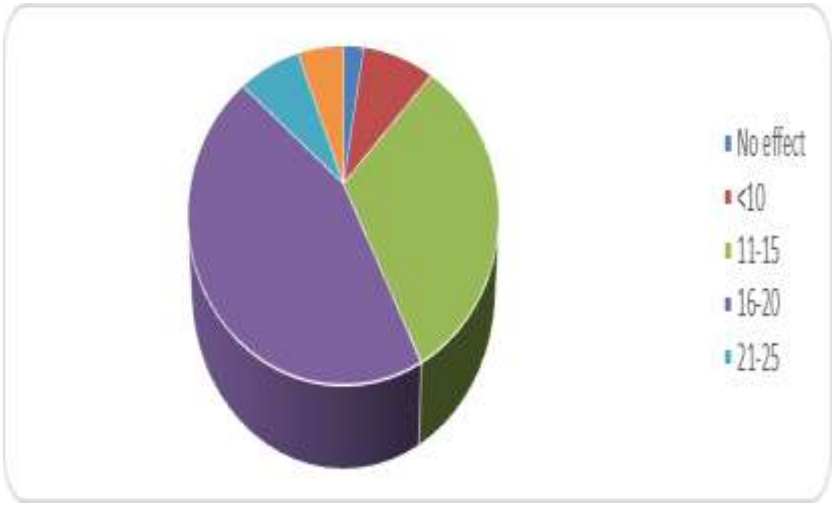

Figure 3: Onset of drug action in study patients.

The total of 158 patients were include in the study in that 69 (43.6%) patients shows maximum of onset of drug action(ODA) in the range of 16-20minutes, 9(5.6%) patients shows minimum of drug action between 20-30 minutes and 4(2.5%) with no effect. The mean of onset of drug action is 14.9±33.3.

Table 1: Demographic profile of parturient women.

Maternal parameter	MEAN ±SD
Age	25±21.3
Gestational week	37.3±16.4

Systolic bp	132.5±77
Diastolic bp	84.8±72
Pulse rate	89.2 ±49.5

The age group in the present study was ranged between 21-23 with 44 patients (27.8%) with the mean 25±21.3. The mean gestational week was 37.3±16.4. The gestational week in the study ranged between 37-39 with 87 (55%) patients. The mean systolic and diastolic BP and PR in the study parturient was ranged 132.5±77.8, 84.8±72 and 89.2±49.5 respectively.

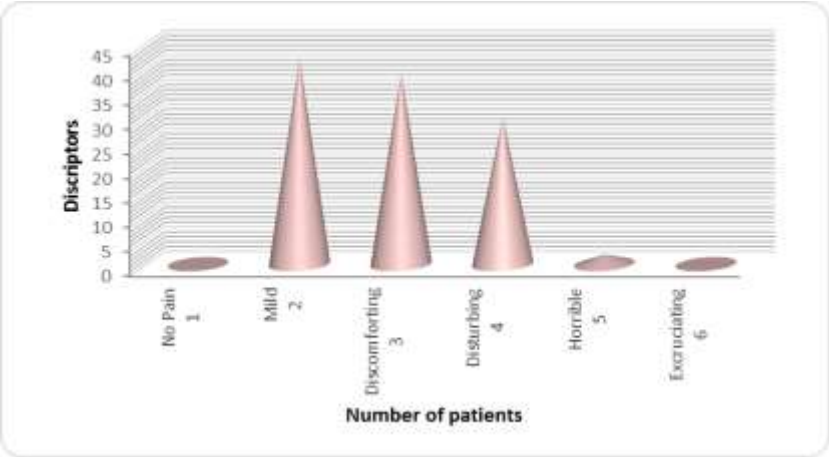

Figure 4: Distribution of subjects according to the extent of pain relief.

All total of 158 patients, 42 patients shown mild pain and 39 had discomforting pain and 30 had distressing pain and 2 with horrible pain. None shows excruciating pain.

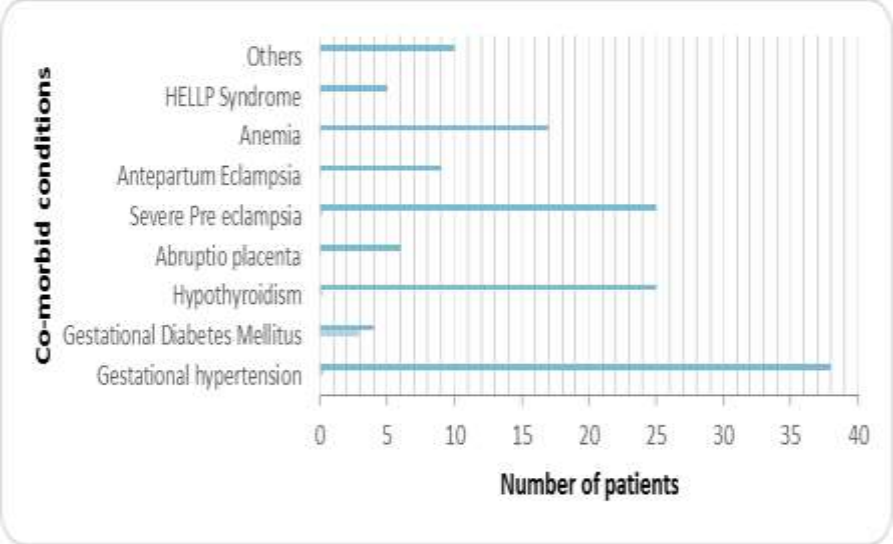

Figure 5: Distribution of patients according to obstetrics and medical disorders during present pregnancy.

Among 158 patients, 24 patients present with no co-morbidity and 134 patients shown co-morbidity, in that 38 (28.3%) patients had Gestational hypertension. Hyperthyroidism and Severe pre-eclampsia were 25 (18.6%) and 25 (18.6%) respectively.

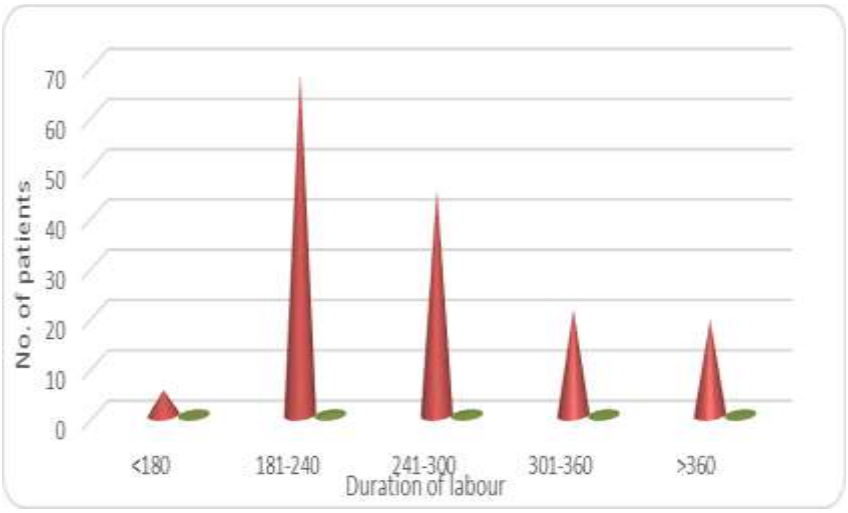

Figure 6: Distribution of studied subjects according to duration of labour.

Among 158 patients, maximum patients i.e., 68(43%) had total duration of labor between 181-240 minutes and 5 patients i.e., 3.1% of women had total duration of labor less than 180 minutes.

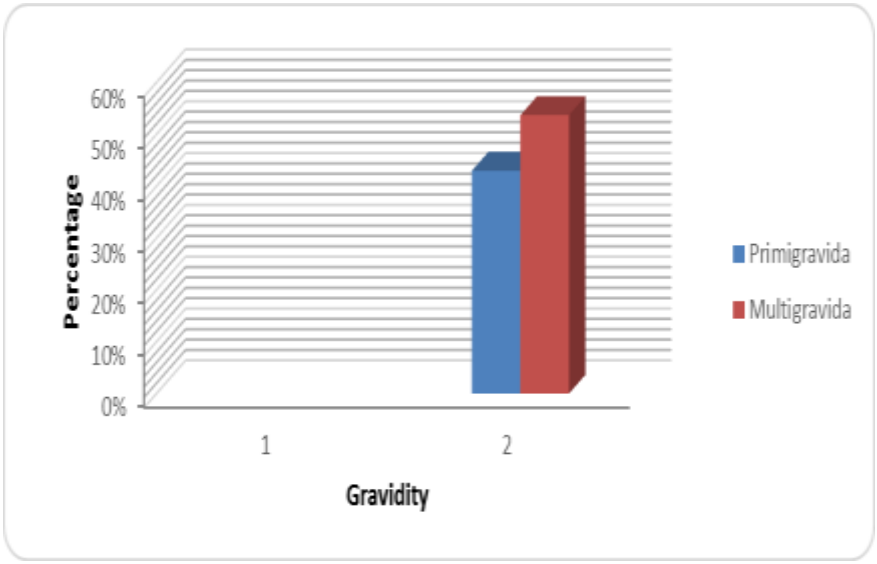

Figure 7: Distribution of subjects according obstetric score.

Total of 158 patients, 63 parturient are with primigravida and 85 with multigravidity.

Table 2: Distribution of foetus according to the use of analgesic use.

Table 2a: Showing the birth weight of new born.

Birth weight	Number of fetus	Percentage
0-1	0	0
1.1-2	31	19.6%
2.1-3	90	57%
3.1-4	37	23.4%

Of all 158 neonates, 90 babies had maximum birth weight ranges between 2.1-3 (57%) and 23.4% i.e., 37 had birth weight ranges between 3.1-4. The mean birth weight of neonates was 2.5±4.7.

Table 2b: Showing the fetal heart rate of new born.

Fhr	Number of patients	Percentage%
90-110	2	1.2%
111-130	14	8.8%
131-150	139	88%
151-170	2	1.2%
171-190	1	0.6%

Among 158 neonates, 139(88%) had maximum fetal heart rate ranges between 131-150 and minimum FHR ranges from 171-190 i.e., 1 patient (0.6%). The mean FHR was 139±51.3.

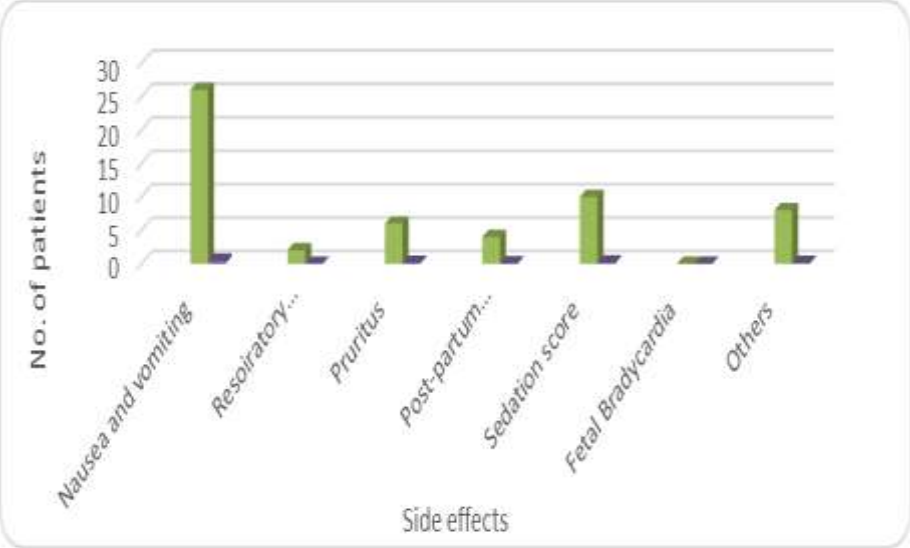

Figure 8: Distribution of subjects according to side effects.

Totally 158 subjects were enrolled in the study in that 55 patients shown side effects and 103 with no side effects. Majority of subjects, 26(47.2%) had nausea and vomiting as major side effect. 10 patients (18.1%) had sedation score, 6 (10.9%) had pruritus, 4(7.2%) had post-partumhemorrhage (PPH), 1 with respiratory depression and none with neonatal depression.

DISCUSSION

Many pregnant women tend to take various analgesic drug for pain relief and minor ailment during pregnancy which will have a deleterious effect on the developing fetus. Depending on the developing fetus, analgesic treatment may be unavoidable during pregnancy but it will inevitably expose the unborn child to the effects, whether pharmacological or toxic effect of the analgesic drug. Thus analgesic given during pregnancy must be benefical to the mother without producing unwanted complication to the developing fetus.

Present study was prospective study undertaken to study the safety and efficacy of tramadol hydrochloride which is as intrapartum labor analgesic. The effect of it on pregnancy and outcome of pregnancy was studied. A total of 158 patient were included in the study. In our own study majority of pregnant women were in between the age group of 21-23(27.8%) followed by those in age group of 24-26 (19.6%).Majority of them were primigravida consisting about 85% of study population whereas result reported by B. Vidhya *et al.*, were in between the age group of 21-25.

Nausea and vomiting are the major side effect of tramadol usage in pregnancy. The percentage of nausea and vomiting, sedation score, pruritus in this study are higher (n=26, 472%),(n=10, 111%) and (n=6,10.9%) respectively, but in contrast to this study, which was conducted in Islamabad by Habib. F *et al.*

Among the study population of 158 patients, it was noted that 42 had mild pain and 39 had discomforting pain and 30 had distressing pain which is parallel to the study done in Chennai by Vaishnavi. V. S *et al.*

In the present study, time required for the onset of analgesia was 14.9±33.3 minutes. It was 15.35±2.65 minutes in study conducted by Patil. S *et al.*,[1] The average duration of labor in this study 181-240 minutes for about 68 patient (43%) in parallel to the study conducted in Bellary by Asha RK. *et al.*, where total labor duration is 3-6 hours. The most common co-morbidity condition are found to be Gestational Hypertension, Severe Pre-eclampsia, Hypothyroidism and Anemia constitute about 28.3%, 18.6% and 18.6% respectively whereas B.P Vidhya *et al.*, carried out a study in which oligohydramnios, IUGR, Anemia are the major co-morbidity conditions.

CONCLUSION

From the present study, it can be concluded that tramadol hydrochloride is an effective analgesic drug which can be used for labor 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 labor pain thereby decreasing the agony of parturient. The overall duration of labor is also significantly reduced with the use of tramadol. Hence intramuscular injection of tramadol hydrochloride could be considered as a safe and effective analgesia in labour.

None of the study subject had severe adverse outcome like APH, PPH and there were no cases of still birth, birth defect and other major congenital anomalies in the neonates of pregnant women exposed tramadol analgesic in this study.

AKNOWLEDGEMENT

The authors are thankful to Dr. Nagendra Rao, Principal, SCS College of Pharmacy, Harapanahalli, for the encouragement and valuable support throughout the study.

Author's contribution

All authors have contributed equally.

Conflict of interest

All the authors declare no conflict of interest.

Ethics declaration

The protocol was verified by the Institutional Ethics Committee of SCS College of Pharmacy. Informed consent was obtained from all the residence in the hospital.

Consent for publication

All authors have given their consent for publication.

Competing interests

The authors declare that they have no competing interests.

Authors funding

The authors hereby declare that no financial support was taken from anyone for research, authorship and for publication of this article.

BIBLIOGRAPHY

1. Patil S, Somashekara SC, Goud GK, Bhanurekha S, Reddy LJ, Deepalaxmi S. Tramadol analgesia in labour. Int J Pharm Biomed Res, 2012; 3(1): 49-51.
2. Lakshman DT, Lakshman DK. Usefulness of tramadol as an analgesic during labour: A clinical study at a tertiary care hospital. Int J Clin Obstet Gynaecol, 2019; 3(6): 280-5.
3. Vaishnavi VS. A prospective study on injection tramadol hydrochloride as a labour analgesic and its effect on duration of labour (Doctoral dissertation, Madras Medical College, Chennai).
4. Khalil RY, Faraj GK. A Comparison of Tramadol and Pethidine Analgesia on the Duration of Labour. Disease and Diagnosis, 2021; 30, 10(1): 1-6.
5. Garg N, Vanitha VG. A randomized controlled trial of intravenous paracetamol and intravenous tramadol for labour analgesia. Obstetrics and Gynecology Research, 2019; 2(2): 3-13.
6. Aimakhu CO, Saanu OO, Olayemi O. Pain relief in labor: a randomized controlled trial comparing intramuscular tramadol with intramuscular paracetamol at the University College Hospital, Ibadan, Nigeria. Tropical Journal of Obstetrics and Gynaecology, 2017; 3, 34(2): 91-8.
7. Ahmed A. Comparison of intramuscular tramadol with intramuscular pentazocine for labour analgesia in Kano, North-Western Nigeria. Faculty of Anaesthesia, 2013.