IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS)
e-ISSN:2278-3008, p-ISSN:2319-7676. Volume 13, Issue 4 Ver. I (Jul – Aug 2018), PP 73-79
www.iosrjournals.org

Study on Use of Intramuscular Tramadol as Analgesic during Labour

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Abstract:*The aim of study is to study the use of intramuscular tramadol as analgesic during labor. Prospective observational study conducted in a total of 51 patients, enrolled from labor ward of obstetrics and gynaecology of RMMCH who are in labor and administered with 100mg intramuscular tramadol as analgesic and with no other complications. The following points were observed to assess the safety and efficacy of intramuscular tramadol as analgesic during labor, they are:[1] age wise distribution of subjects, [2] demographic profile of parturient women, [3] onset of analgesic activity, [4] extent of pain relief using McGill's score, [5] evaluation of APGAR score to assess the impact of analgesic effect on foetus, [6] quantum of use of tramadol as Defined Daily Dose (DDD) [7] identification and documentation of adverse effects, if any. In our study majority of the subjects were in age group 24-29 with mean gestational age 36±2.25 weeks. Systolic and diastolic blood pressure of all subjects is within the normal range. 63% of cases shows onset of action within 16-20 minutes. APGAR scores was in between 4-6 at one minute and 7-9 at five minutes. APGAR score was less than 4 in five babies at one minute and the number reduced to one after 5 minutes. The quantum of use of tramadol as DDD is higher than the assigned DDD. Incidence of ADR observed is 5.8%. Most of the patients experienced discomforting and distressing pain and none experienced horrible and excruciating pain on 100mg intramuscular dose of Tramadol.Our study suggests that therapeutic dose of tramadol intramuscular can be recommended as labour analgesia. It is simple to use and causes significant pain relief with minimal side effects.*

Key words:*intramuscular tramadol, analgesic, labor, demographic profile, McGill's score, APGAR score, Defined Daily Dose*

Date of Submission: 02-07-2018 Date of acceptance: 18-07-2018

I. Conclusion

Though pain may be forgotten, pain of labour represents severe physiological stress which can result in maternal acidosis and hormone imbalance including catecholamine release. This causes adverse effects on mother as well as baby. Hence, woman in labour are given with analgesics.

In our study majority of the subjects were in age group 24-29 with mean gestational age 36±2.25 weeks. Systolic and diastolic blood pressure of all subjects is within the normal range. There are no significant changes in maternal cardio respiratory parameters.

63% of cases shows onset of action within 16-20 minutes.

APGAR scores were in between 4-6 at one minute and 7-9 at five minutes. APGAR score was less than 4 in five babies at one minute and the number reduced to one after 5 minutes. The babies tolerated well to the birthing process and there is no impact of analgesic effect of tramadol on foetus.

Our study revealed that quantum of use of tramadol as DDD is higher than the assigned DDD. Hence, use of tramadol was more in our hospital. However, the sample size low to make a clear cut conclusion

Incidence of ADR observed is (5.8%). The ADRs observed were nausea and sedation. ADRs were tolerable by the mother and none reported discomfort.

Outcome of the study reveals that most of the patients experienced discomforting and distressing pain and none experienced horrible and excruciating pain on100mg intramuscular dose of Tramadol.

Our study suggests that therapeutic dose of tramadol intramuscular can be recommended as labour analgesia.It is simple to use and causes significant pain relief with minimal side effects. It doesn't affect the health of mother as well as baby. It is also listed in Medecins San Frontieres,2016 essential drug list.

II. Introduction

Pain is a subjective phenomenon. It is perception rather than a sensation. The various methods used to assert the pain are usually referred to as 'Analgesimetry'. Normally pain is a defence mechanism of our body but in labour when it exceeds intensity and duration, it produces harmful effects on both mother and foetus. Pain causes tension and fear which in turn causes anxiety and stress. This leads to hyperventilation and increased sympathetic activity which leads to foetal acidosis, prolonged labour and so adverse outcome**[1]**.

Labor pain is emotional experience and involves both physiological and psychological mechanisms[2]. Pain during the first stage of labor originates predominantly due to cervical dilatation and uterine muscle wall ischemia leading to lactate accumulation. During the late first stage and second stage of labor, the vagina and perineum form additional sources of pain. The associated increase in sympathetic activity leads to increased oxygen consumption, respiratory alkalosis, and metabolic acidosis which could lead to decreased oxygen being transferred to the fetus. Thus, pain relief during labor is expected to reduce maternal stress and improve maternal and perinatal outcome. Obstetric analgesia and anaesthesia have evolved from vague possibility to reality[3]. Non pharmacological methods includes Transcutaneous electrical nerve stimulation (TENS), Relaxation/breathing techniques, Temperature modulation: hot or cold packs, water immersion, Hypnosis, Massage, Accupunture, Aromatherapy and pharmacological techniques include inhaled agents such as Meperidine[pethidine} 1mg/kg IM, Morphine 0.1-0.15mg/kg,Dimorphine 5-7.5mg, Fenatyl1-2µ/kg, Tramadol 0.1-0.3g IM and regional techniques such as Caudal analgesia and LumbarEpidural analgesia[4].

Tramadol is a modestly potent opioid analgesic which interacts with MU; Delta and Kappa opioid receptors, where it exhibits purely agonist effects. Tramadol is aneffective and well tolerated agent to reduce pain resulting from trauma, renal or biliary colic and labour, and also for the management of chronic pain of malignant or non-malignant origin, particularly neuropathic pain. Tramadol appears to produce less constipation and dependence than equal analgesic doses of strong opioids. It has been suggested that tramadol should be strongly recommended in labour analgesia. It is simple to use compared to epidural labour analgesia. It causes significant pain relief. It does not alter mode of delivery. It does not affect the health of the mother as well foetus. It does not prolong average duration of labour. It has fewer side effects[5].

Intramuscular tramadol 100mg, but not 50mg, provided pain relief equivalent to that with 50mg of pethidine[6]. With pethidine, adverse effects were more frequent and respiratory function of neonates were significantly lower. Tramadol is having less cardiovascular and respiratory depressant[7].

Our study is performed to assess the safety and efficacy of intramuscular tramadol as analgesic during labour whose results and conclusion can be used for further reference and the use of intramuscular tramadol in RajaihMuthaih Medical College Hospital can be compared with that of other hospitals.

III. Methods

The study was a non-invasive, observational, prospective, cohort study carried out over 6 month period incorporating both descriptive and inferential analyses. The study was approved by the Institutional Human Ethics Committee & Informed Consent Form was obtained from the eligible patients and a total of 51 partruients were selected on the basis of inclusion criteria and exclusion criteria.

Inclusion criteria:

- Patients in labour who are administered with intramuscular tramadol as analgesia.

Exclusion criteria:

- Parturients with no other obstetric complication.
- Patients who are not willing to participate.

SOURCES OF DATA:

The data will be collected from the patients admitted for fine confinement in labour ward of obstetrics & gynaecology of RMMCH. The various sources used for collection of data include:

- Patients case sheets maintained in the hospital.
- Patient interview.

Once the patient is in established active phase of labour i.e., ≥3 centimeters dilatation, full effacement with good uterine contractions, vital signs recorded and primary investigations done and pain score was noted after administering the drug. Injection tramadol 100 mg IM was given as a single dose depending on condition of the patient i.e., 2 mg/ Kg/ body weight. Pulse rate, respiratory rate, blood pressure, FHR were recorded. Patient was advised to inform as soon as pain begins to decrease in intensity or even if there is no pain relief at all. Partogram was marked to assess the progress of labour.

The following observations were recorded:

1.Onset of action of the drug 2. Drug side effects, change in vital parameters at first every 30 min, then at hourly were monitored. 3. FHR monitoring was done clinically and any variability noted. 4. Progress of labour was monitored clinically. 5. Assessment of analgesia was done hourly by scoring system, injection

repeated every 3 hours, not exceeding 400 mg/ day. 6. Patient level of consciousness, alertness, and psychological disturbances was judged. 7. The duration of labour, degree of pain relief in first and 2nd stage, the total dose of tramadol given, the mode of delivery and recovery time in each patient was noted and recorded. 8. Apgar score at 1 and 5 minutes interval after delivery of neonate was recorded. 9. Any complications during the course of labour were recorded. Patient was observed for 2 hours after delivery and was shifted to the ward if there were no complications.

Assessment of pain relief:

The McGill Pain Questionnaire can be used to evaluate a person experiencing significant pain. It can be used to monitor the pain over time and to determine the effectiveness of any intervention. It was developed at by Dr.Melzack at McGill University in Montreal Canada and has been translated into several languages[8].
In our study degree of pain relief was assessed by using Present Pain Intensity (PPI) scale of McGill's Pain

Questionnaire which states:

Evaluative		
0	No pain	
1	Mild	
2	Discomforting	
3	Distressing	
4	Horrible	
5	Excruciating	

DEFINED DAILY DOSE

The DDD is the assumed average maintenance dose per day for a drug used for its main indication in adults.

Steps:

- Find out the total amount of medicines used or procured in one year in terms of the number of units (tablets, capsules, injections) and the strength (mg, g (gm), IU).
- Calculate the total quantity consumed in one year in terms of mg/g/I.U. by multiplying the number of units (tabs, caps, inj.) by the strength of dose.
- Divide the total quantity by the assigned DDD for that medicine.
- Divide the total quantity by the number of patients (if known) or by the population[9].

IV. Results and Discussion

Inour study, 51 partruient women were studied to evaluate safety and efficacy of Tramadol hydrochloride.

Table 1: AGE WISE DISTRIBUTION OF SUBJECTS

Sl.No	Age(years)	No.Of Subjects	Percentage
1.	18 - 23	16	31%
2.	24 - 29	23	45%
3.	30 - 35	10	20%
4.	36 - 41	2	4%

Totally 51 subjects were enrolled in the study and all the 51 patients completed the study. Majority of the subjects falls in age group 24-29(45%) followed by 19-23(31%).

All the patients are in gestational age 36 ± 2 weeks. Systolic and diastolic blood pressure of all subjects is within the normal range. There are no significant changes in maternal cardio respiratory parameters.

Table 2: DEMOGRAPHIC PROFILE OF PARTURIENT WOMEN

Sl. No.	Demographic Profile	Mean ± SD
1.	Age(years)	26 ± 4
2.	Weight(KG)	58.74 ± 6.71
3.	Gestational Age (weeks)	36 ± 2.25
4.	Systolic Blood Pressure(mm/Hg)	116 ± 7
5.	Diastolic Blood Pressure (mm/Hg)	76 ± 6
6.	Pulse Rate (Beats/min)	84 ± 4

In a total of 51 patients, 32 patients (63%) has onset of action within 16 – 20 minutes followed by 21 – 25 minutes in 20% of cases with 100mg of intramuscular tramadol.

Fig.1: ONSET OF ACTION

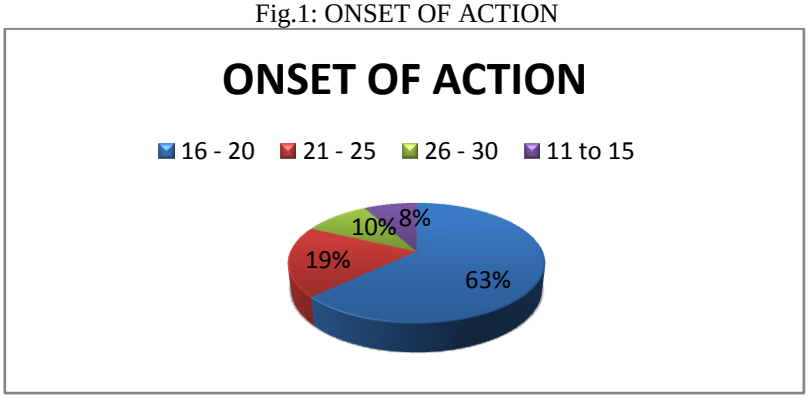


Table 3: EXTENT OF PAIN RELIEF

Sl.No.	Descriptors	Pain score	No. Of Cases
1.	No pain	0	-
2.	Mild	1	4
3.	Discomforting	2	31
4.	Distressing	3	16
5.	Horrible	4	-
6.	Excruciating	5	-

All of 51 subjects, after 1hr of administration of 100mg intramuscular tramadol, 31 subjects experienced discomforting pain, 16 subjects experienced distressing type of pain and 4 patients experienced mild pain. None experienced horrible and excruciating pain.

Fig.2: EXTENT OF PAIN RELIEF

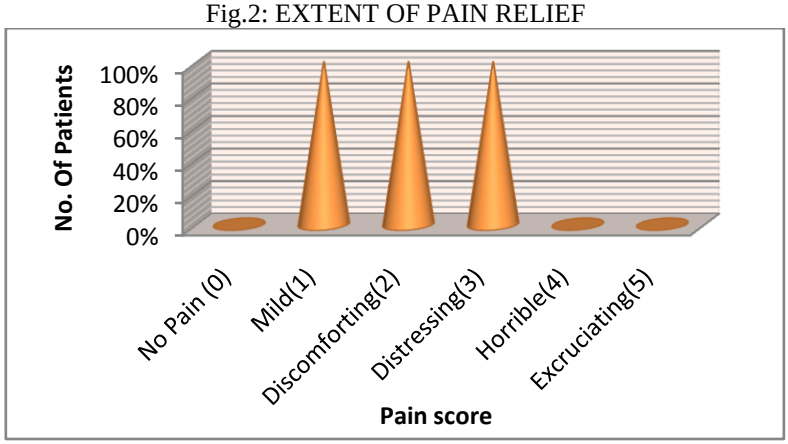
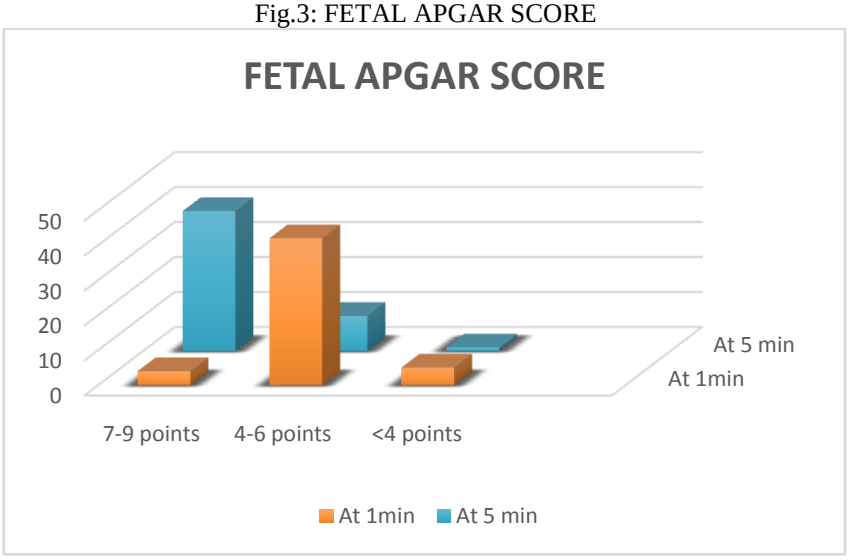


Table 4: ANALGESIC EFFECT ON FOETUS

APGAR Score	No.Of.Subjects	Percentage
At 1st min		
7 – 9	4	7.8
4 – 6	42	82.3
<4	5	9.8
At 5 mins		
7 – 9	40	78.4
4 – 9	10	19.6
<4	1	1.9

In majority of babies APGAR scores was in between 4-6at one minute and 7-9 at five minutes.APGAR score was less than 4 in five babies at one minute and the number reduced to one after 5 minutes.

Fig.3: FETAL APGAR SCORE



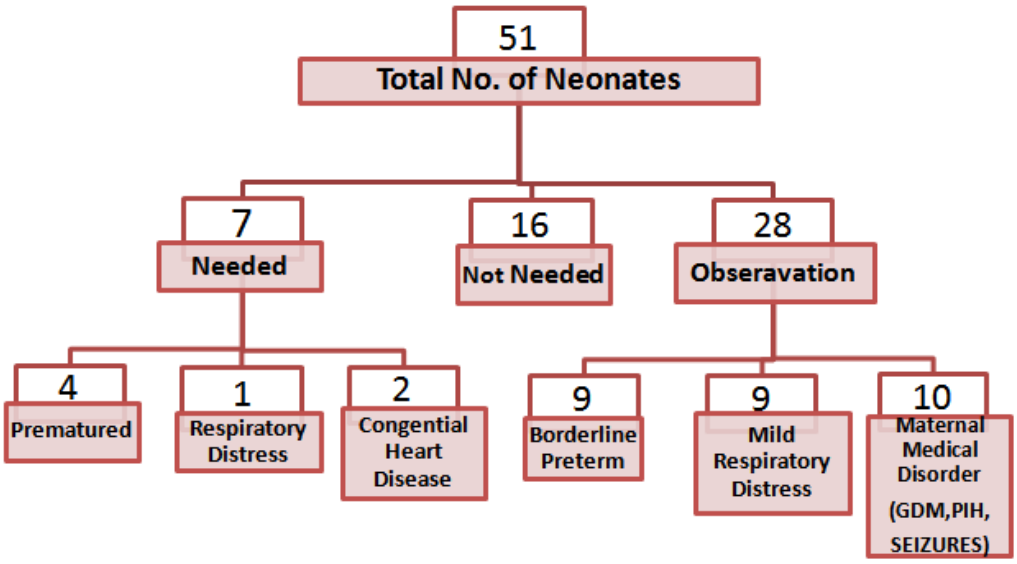
Of all 51 neonates, 16 didn't required NICU admission, 7 were admitted and 28 were under observation. Admissions were done in the view of premature delivery -4, respiratory distress (RD) -1, and congential heart disease (CHD) -2.

Table 5: NICU ADMISSIONS

TOTAL No. OF NEONATES	No. OF ADMISSIONS		
	NEEDED	OBSERVATION	NOT NEEDED
51	**7**	**34**	**10**

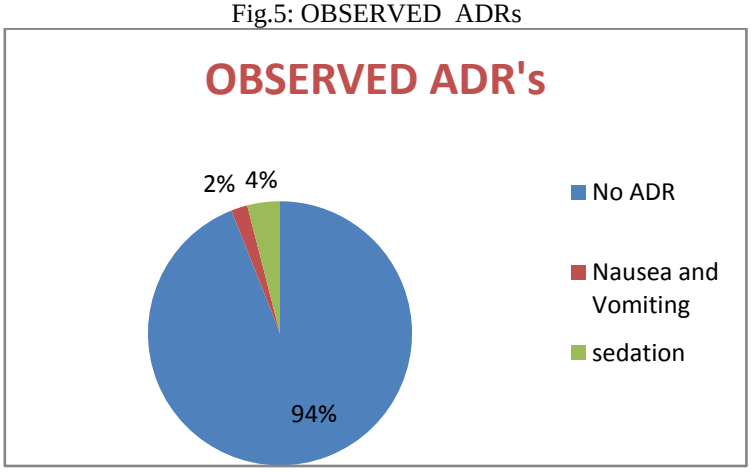
All of 34 NICU observations, 9 were observed in view of borderline pre-term delivery, 9 for mild respiratory distress (RD) and 10 for maternal medical disorders such as GDM, PIH, Seizures.

Fig.4: NICU ADMISSIONS



In the study, among 51 patients, 48 patients have no side effects. Only 1 patient has nausea and vomiting and 2 patients were observed with sedation.None of the side effects the progress of vital parameters.

Fig.5: OBSERVED ADRs



INCIDENCE PROPORTION

$$\frac{\text{Number of new cases of disease or injuryduring specified period}}{\text{Size of population at start of period}}$$

No .of new cases of ADR's = 3

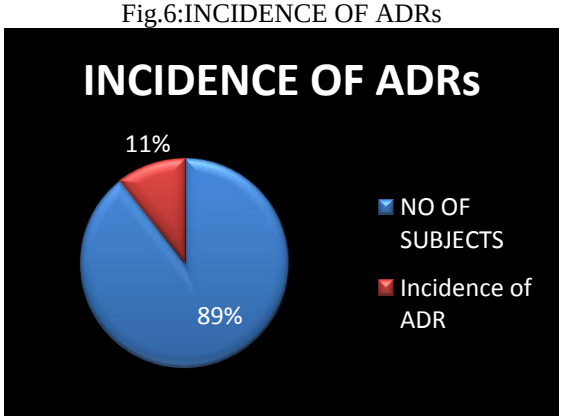
Size of population = 51

Incidence proportion = (3/51)*100

=5.8%

A total of 51 subjects, 6% have the probability of developing adverse drug reaction.

Fig.6:INCIDENCE OF ADRs



DEFINED DAILY DOSE

No. of units of tramadol used during study period = 62 ampoules
Total quantity consumed during trial period = 62 x 100 mg
= 6200 mg
= 6.2 g
Assigned Defined Daily Dose = 0.3 g
Total quantity consumed = 6.2 g

$$\frac{\text{Assigned DDD } 0.3\text{g}}{}$$

= 20.66 g/51 patients
= 40.50 g/100 patients

Table 6: DEFINED DAILY DOSE

DRUG	ATC CODE	Prescribed strength	Assigned DDD	Total Quantity consumed (mg)	Total DDDs/Assigned DDD	DDD/51 Patients
Tramadol	NO2AX02	100 mg	0.3 g	6200 mg	20.66 g	0.40 g

As part of our study, DDD/51 patients were calculated according to DTC(Drugs and Therapeutic Committee-guide) with reference from WHO Recommended ATC Classification and found that DDD/51 patients are 0.40g.

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IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS) is UGC approved Journal with Sl. No. 5012, Journal no. 49063.

Akshay Kumar Andey "Study on Use of Intramuscular Tramadol as Analgesic during Labour." IOSR Journal of Pharmacy and Biological Sciences (IOSR-JPBS) 13.4 (2018): 73-79.