

Research Article**Role of Tramadol in Labor Analgesia****Dr. M. Suguna Shobha Rani¹, Dr. K. Vara Prasad²**¹Assistant Professor, Department of Obstetrics and Gynaecology, Government Medical College, Anantapuramu-515001²Assistant Professor, Department of Microbiology, Government Medical College, Anantapuramu-515001***Corresponding author**

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Abstract: The aim of the present study to assess the efficacy and safety of intramuscular tramadol hydrochloride as an analgesic during labor. Its efficacy has compared with placebo group. This is a prospective study conducted for 1 year on 100 pregnant women in labor at term. They were alternatively divided into two groups. The study group (n=50), received 100mg i.m tramadol and the control group (n=50) received 2cc placebo. They are observed for time of onset of analgesia and duration, maternal cardio respiratory parameters, fetal Apgar score, side effects of tramadol, mode of delivery. In majority of cases (80%), pain relief was within 16.27 min on intramuscular dose of 100mg of tramadol and duration of analgesia was 3.78 hours. Good Pain relief was observed in 49% and moderate pain relief was in 12%. No significant changes in the fetal heart rate pattern or maternal cardio respiratory parameters were noted with tramadol. Majority of them did not suffer any side effects of tramadol, only 7% has complained of restlessness, dizziness, headache and 3.5% had nausea and vomiting. The study showed that the overall duration of labor was decreased in study group (4.13 hours) when compared to control group (6.24 hours). Apgar scores of most of the babies at 1min and 5 min were satisfactory and although seven babies (14%) in the tramadol group and 5 babies (10%) in the placebo group were observed that score is 6-7.**Keywords:** Tramadol hydrochloride, Labor analgesia, Placebo.

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 defense mechanism of our body but in labor when it exceeds intensity and duration, it produces harmful effects on both mother and fetus. Pain causes tension and fear which in turn causes anxiety and stress. This leads to hyperventilation and increased sympathetic activity which leads to fetal acidosis, prolonged labor and so adverse outcome.

Labor pain is a result of many complex interactions, physiological and psychological, excitatory as well as inhibitory. The pain if not adequately controlled may affect respiratory, cardiovascular, gastrointestinal, urinary and Neuro-endocrine functions due to segmental and supra segmental reflexes. Pain also reduces utero-placental blood flow leading to altered fetal homeostasis [1].

Effective analgesia during labor will prevent these avoidable consequences. There are several methods used for the control of labor pain. They include use of various drugs viz., general anesthetics like ether, enflurane, isoflurane, desflurane, ketamine and opioid analgesics like morphine, pethidine, fentanyl, buprenorphine. And also

various techniques is being used for the delivery of these drugs viz., inhalational anesthesia, epidural analgesia, local anesthesia, patient controlled epidural and intravenous anesthesia [2].

There are major drawbacks to the above methods, as they are not practicable at the rural Indian setup, as majority of the deliveries are conducted in primary health centers. Therefore there is a need of a safe and effective analgesic with minimal maternal and fetal side effects. And also, it should be very simple technique to administer.

A relatively new addition to the international analgesic armory is Tramadol. Tramadol is a modestly potent opioid analgesic which interacts with MU; Delta and Kappa opioid receptors, where it exhibits purely agonist effects. Tramadol is an effective and well tolerated agent to reduce pain resulting from trauma, renal or biliary colic and labor, and also for the management of chronic pain of malignant or nonmalignant origin, particularly neuropathic pain. Tramadol appears to produce less constipation and dependence than equianalgesic doses of strong opioids. It has been suggested for use in obstetrics because of its rapid and profound analgesia. It does not arrest labor and has wide margin of safety.

Intramuscular tramadol 100mg, but not 50mg, provided pain relief equivalent to that with pethidine 75mg [3]. With pethidine, adverse effects were more frequent and respiratory function of the neonates was significantly lower. Tramadol is having less cardiovascular and respiratory depressant [4]. Therefore, the present study has been undertaken to assess the safety and efficacy of tramadol hydrochloride intra muscular (I.M) injections as analgesia for labor.

MATERIALS AND METHODS

This is a prospective study conducted from September 2008 to September 2009 at Niloufer Maternity Hospital, Red Hills, and Hyderabad. In this study 100 term pregnant women in active labor without any obstetrical and medical complications were included. Patients with multiple gestation, previous caesarean section, abnormal presentation and fetal complications like IUGR, congenital abnormalities were not included in the present study. Ethical Committee has approved and Consent for labor analgesia from all patients has taken. A complete history has taken from all the patients and complete examination has done. All preliminary routine investigations are done. Procedure and side effects of the drug are explained.

The 100 women were alternately divided into:

Group A – Study Group: 50 women in active labor who received 100 mg tramadol intramuscularly.

Group B – Control Group: 50 women in active labor who received Inj.2 cc Placebo intramuscularly.

A Partogram is initiated. Pain relief score is recorded according to Oxford score. During the procedure, monitoring of PR, BP and RR was recorded every hour and frequency, duration and intensity of contractions are

noted and fetal heart rate is monitored every half an hour during the 1st stage of labor and every 15 minutes during the 2nd stage of labor, progress of labor checked periodically.

Patient enters into the study when cervix is effaced and 3 cm dilated, 100 mg Intramuscular dose of tramadol is given. Top up dose of Tramadol 50 mg is given slowly. It can be repeated 50 - 60 minutes. After the 1st dose, pain relief of mother was assessed by noting down pain intensity. Labor, if induced by oxytocin or prostaglandins was noted. Mode of delivery whether normal, instrumental or operative was studied. Any maternal side effects, if present are noted, perinatal outcome evaluated by Apgar score. All resuscitative measures for mother and baby are kept ready. Total duration of labor and injection delivery interval is calculated.

RESULTS

In our Institution on an average, nearly 500 deliveries occur per month. Out of them 40% are delivered by caesarean section, 60% are vaginal deliveries. Among 50 Group A (Study Group) Pregnant women, 20 members were in the age group of 15-20 years, 22 and 8 members were in the age group of 21-25 years and 25-30 years respectively. Tramadol has only negligible effect on the systemic circulations (Fig.No:1). Tramadol causes only a slight increase in Blood pressure and Heart rate. There was slight increase in Systolic B.P from 1-30 mm HG, the maximum(56%) being in the range of 11-20 mm HG. Slight increase in Diastolic B.P from 1-30 mm HG, the maximum (60%) being in the range of 21-30 mm HG.

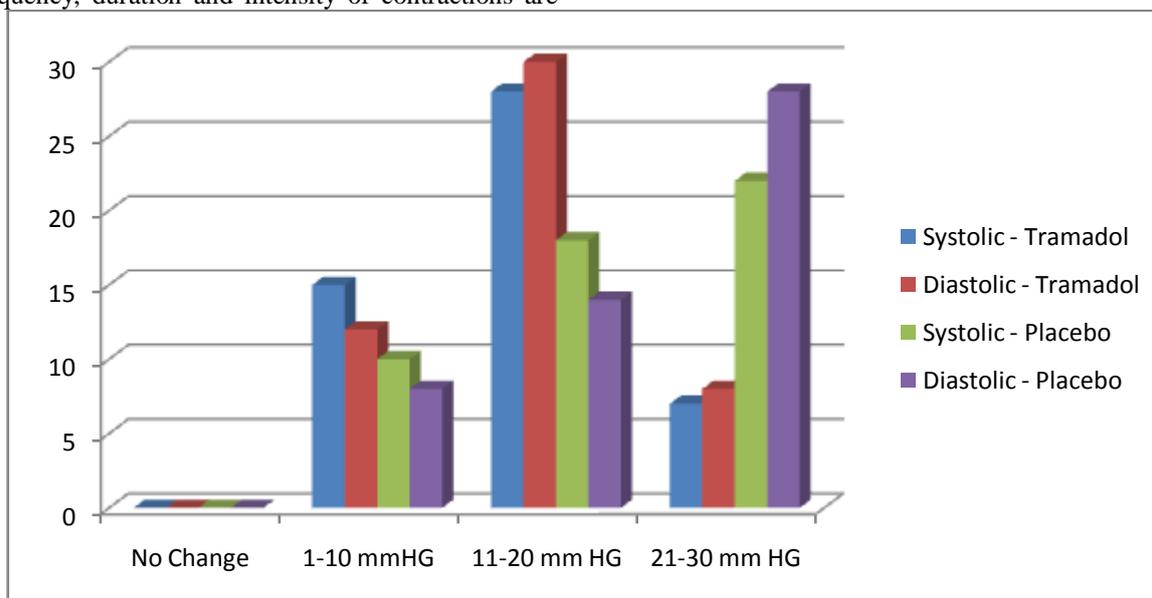


Fig 1: Change in Blood pressure in Study and Control Group

The P value by Chi Square test is < 0.05 and is statistically significant. Maternal heart rate has increased in most of the cases (92%) by 1-5 beats/min.

There was no change in the respiratory rate in cases and controls. In majority of cases (80%), pain relief was within 16.27 min with intramuscular dose of 100mg of tramadol and duration of analgesia was 3.78 hours. Pain

relief was moderate (Score - 3) to good (Score - 4) of respectively. Amongst controls there was no relief of pain. Oxford score in the study group 12% and 49%

Table-1: showing Mode of delivery among study and control group.

| Mode of Delivery | No. of Women | |
|----------------------------|--------------|----------|
| | Group A | Group B |
| Normal | 46 (92%) | 36 (72%) |
| Instrumental | 2 (4%) | 6 (12%) |
| Caesarean section | 2 (4%) | 8 (16%) |
| Oxytocin and Prostaglandin | 9 (18%) | 10 (20%) |

The study showed that the overall duration of labor was decreased in study group (4.13 hours) when compared to control group (6.24 hours). In the present study Apgar score was good about 86% of study group shows score 8-10 and 90% of control group showed score 8-10.

Table 2: Comparison of various methods among Study and control group

| | No. of Women | |
|-------------------------------|------------------|------------------|
| | Group A | Group B |
| Injection - delivery interval | 1-3 hours in 32% | 1-3 hours in 38% |
| Action phase | 3-5 hours in 30% | 3-5 hours in 30% |
| APGAR Score (6-7) | 7 (14%) | 5 (10%) |

The P value by Chi square test is < 0.05, it is statistically significant. Side effects of tramadol are very minimal (Table no.4). Side effects occur particularly when the patient is subject to physical stress.

Table 3: Side effects of Tramadol (100mg)

| S.No. | Side Effects | Group A | Group B |
|-------|---|---------|---------|
| 1 | No Side effects | 25(89%) | 18(64%) |
| 2 | Nausea & Vomiting | 1(3.5%) | 1(3.5%) |
| 3 | Optical hallucinations | - | - |
| 4 | Palpitations | - | 1(3.5%) |
| 5 | Restlessness, dizziness, Sweating, Headache | 2(7%) | 2(7%) |

The two groups are compared statistically of the incidence of side effects like sedation, nausea, vomiting the P value is < 0.01, < 0.05 and < 0.05 successively and hence is statistically significant. Top-up dose of Tramadol is required was only one or two doses in most of the cases, but only 2 cases (9%) has required 3 doses of Tramadol.

DISCUSSION

Pain during labor increases maternal oxygen consumption, cardiac output and catecholamine levels. The relief of pain during childbirth has been of great interest through ages to both physician and public. Majority of women were in the age group 21 to 25 years and there was no statistically significant difference in the two groups regarding gravidity or gestational age. In the study by Jain *et al.*; [5] and by Li and Weng L *et al.*; [6] all women were primigravida. In the study by Bajaj *et al.*; [7] all 100 women were in the gestational age of 37 to 42 weeks.

No significant changes in the fetal heart rate pattern or maternal cardio respiratory parameters were noted with tramadol. Keskin *et al.*; [8] and Li and Weng [6] also did not observe and change in fetal heart rate. Li and

Weng [6] and Bajaj *et al.*; [7] did not note any change in maternal cardio respiratory parameters.

In majority of cases (80%), pain relief was within 16.27 min with intramuscular dose of 100mg of tramadol and duration of analgesia was 3.78 hours. This is similar to other studies such as Sudha patil *et al.*; [2] reported 15 min, Meen jyothei *et al.*; [9] reported 10 min and Nagaria Tripti *et al.*; [9] observed 15.89 min. The duration of analgesia reported by Sudha patil *et al.*; [2] was 4.10h, Thakur Ratna *et al.*; [10] reported 3.96 h and Husslein *et al.*; [11] reported only 2 h.

Pain relief was moderate (Score - 3) to good (Score - 4) of Oxford score in the study group 12% and 49% respectively. Sudha Patil *et al.*; [2] shown 58% of the parturient had good pain relief. Nagaria Tripti *et al.*; [1] and Meena *et al.*; [9] observed about 37 % and 54% of the parturient respectively.

Majority of cases (92%) received tramadol underwent normal vaginal delivery when compared to those who received placebo (72%). Forceps delivery was 4% in Group A and 12% in Group B. Caesarean section was 4% in Group A and 16% in Group B. Sudha patil *et*

al.; [2] reported 90% normal deliveries, 6% Instrumental deliveries and 4% LSCS.

A good analgesic will reduce the duration of labor and prevent dysfunctional labors. The mean duration of 1st stage of labor was 3 hours and 45 min in the present study. Sarkar and Mukhopadhaya [12] reported similar results in their study. The mean duration of 2nd stage in the present study was 23 min. Meena *et al.*; [9] reported as 17.46 min and Daftary *et al.*; [13] reported it to be 26 min. In our study the mean duration of 3rd stage of labor was 5 min. Daftary *et al.*; [13] reported 4.6 min.

Associated factors and transplacental transmission of the analgesic from mother to fetus can affect the Apgar scores of the babies at birth. Ideal analgesic is the one that has no adverse effect on the fetus. In this study Apgar scores of most of the babies at 1min and 5 min were satisfactory and although seven babies (14%) in the tramadol group and 5 babies (10%) in the placebo group were observed that score is 6-7. While Sudha patil *et al.*; [2] observed that Apgar score was > 7 at 1 min (96%) and 5 min (100%). Bajaj *et al.*; [7] reported an Apgar score of more than 8 at 1 min in all neonates of the tramadol group.

In this study no side effects were seen in 89% among group A and 64% among group B. nausea and Vomiting in about 3.5%. Jain *et al.*[5] observed that sedation was the only side effect in 9% of tramadol group.

CONCLUSION

In this study it is found that the therapeutic dose of tramadol intramuscular is a potent analgesic with rapid onset of action, quick metabolism and good pain relief score. Tramadol decreases the duration of labour and increases duration of analgesia with minimal side effects. It can be easily administer, economical, good therapeutic dose.

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