Comparative Study of Efficacy of Tramadol as an Analgesic in Labor on Primigravida and Mutligravida

*M Suguna Shobha Rani1, K Vara Prasad2

1. Department of Obstetrics and Gynaecology, Government Medical College, Anantapuramu-515001, India.
2. Department of Microbiology, Government Medical College, Anantapuramu-515001, India.

ABSTRACT
Prolonged labor contributes to increased perinatal and maternal morbidity and also increases the chances of C-section. Pain during labor increase exhaustion and psychological burden to mother. Tramadol is a good analgesic with good pain relief and without significant maternal or fetal adverse effects. This study has done to compare the efficacy of tramadol intramuscular injection among primigravida and multigravida and the number of Top ups of Tramadol required. 100 patients were taken up for study. Of these 100 patients both primipara & multipara were included about 50 each. All patients are in gestational age 37-42 weeks. This is a prospective study conducted in private hospital with patients consent as randomized study. Both fetal and maternal side effects are very minimal. Tramadol reduced the duration of labor in all stages, more in multigravida. Pain relief was better in multigravida than primigravida which is significant. Side effects were minimal with tramadol, almost same in primigravida and multigravida. Tramadol reduced the LSCS deliveries. More multigravida underwent spontaneous vaginal deliveries when compared to primigravida. Tramadol is a better analgesic to reduce labor pain and lesser maternal-fetal side effects. Tramadol works more efficiently in multigravida than in primigravida. Both primigravida and multigravida respond better with tramadol as a labor analgesia.

Keywords: Cervical dilatation, labor pain, multigravida, primigravida, tramadol hydrochloride

INTRODUCTION
Pain and agony during childbirth is quite often unbearable and at times beyond description. This pain if not adequately controlled can lead to maternal and fetal complications because of widespread maternal sympathetic activation that causes increase in cardiac output, blood pressure, and pulse rate of the mother. It constitutes danger to the survival & subsequent neurological development of infant. Effective analgesia prevents the pain induced hyperventilation and hypopcapnia which can be severe enough to produce tetany in painful labor. Painful labor also reduces utero-placental blood flow by up to 25%.
Prolonged labor can lead to increased maternal and neonatal mortality and morbidity. The causes of prolonged labor relate to maternal age, induction of labor, premature rupture of membranes, early admission to the labor ward, epidural analgesia and high levels of maternal stress hormones, but are unknown in most cases [1]. The risks for complications of prolonged labor are much greater in poor resource settings [2-4].
The widespread use of antispasmodics help to ensure steady progress of labor reduces the risk of dysfunctional labor and enables early identification of emerging obstetric problems [5]. The requirements of a satisfactory analgesic in labor are safety and effective analgesia throughout the painful periods of labor with no unpleasant maternal side effects and no depressant effect on the baby or on the maternal cardiorespiratory system. The technique...
used should be cheap, easy to administer, produce good relief of pain, but should not impair consciousness and co-operation. It should be non-toxic to the mother and fetus. The technique must have no tocolytic action and should not delay labor.

Tramadol hydrochloride is centrally acting analgesic which has got both opioid and non-opioid mechanism of action. It also causes cervical dilatation and also reduce duration of labor. It activates only 30% of opioid receptors (Kappa and μ). It inhibits noradrenergic uptake and stimulates serotonin release. These have no adverse effect on GIT, respiratory, cardiovascular and central nervous system. As by keeping in mind about the labor effects on mother and fetus we have tried to study on Tramadol intramuscular route as labor analgesia.

The present study assess the efficacy, side effects and safety of tramadol as labor analgesic and also the Tramadol efficacy comparison among Primigravida and Multigravida along with number of top ups required for both primi and multigravida.

MATERIALS AND METHODS

The present study was a prospective, open, interventional study done on 50 members of primigravida and 50 members of Multigravida each. Prior written informed consent was obtained and the study was conducted in a private hospital in the year 2014.

The inclusion criteria were primigravida and multigravida with term gestation (37-41 weeks) without cephalo-pelvic disproportion, in active labor more than 3 cm cervical dilatation and 80% effacement with good uterine contractions (3-4 contractions /10 min, each lasting for 45 sec or more). Women with a history of respiratory disease, hypertension [6], diabetes, epilepsy, psychiatric disease and other high risk pregnancies were excluded from the study.

A primary dose of 100 mg tramadol hydrochloride was given by i.m route during active labor. An additional dose of 50 mg was given to those primigravida who did not respond after 1 h of the primary dose. Top-up doses given every 60 minutes. The following points were noted after the tramadol injection: (i) time of onset of pain relief, (ii) degree of analgesia (iii) duration of labor, (iv) Materno-fetal physiological effects and (iii) adverse effects of tramadol.

The degree of analgesia was noted by oxford score. Fetal heart rate, maternal cardiorespiratory parameters and the progress of labor were monitored at half hourly intervals. Mode of delivery and APGAR scores of the baby at birth, at one min and 5 min were noted. Mothers were monitored for 24 h after delivery for any side effects. Descriptive statistical analysis was used to represent the demographic data.

RESULTS

Both Primigravida and Multigravida in active labor with >3cm cervical dilatation were taken into the study. The parturient basic demographic data are represented in the (Table 1).

Table 1: Demographic data of parturient women (n=100)

<table>
<thead>
<tr>
<th>Demographic Profile</th>
<th>Mean±SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>23.96±6.62</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>55±8</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>149±9</td>
</tr>
<tr>
<td>Gestational age (weeks)</td>
<td>39.8±1.2</td>
</tr>
<tr>
<td>Systolic blood pressure (mm Hg)</td>
<td>118.21±7.68</td>
</tr>
<tr>
<td>Diastolic blood pressure (mm Hg)</td>
<td>80.3±5.97</td>
</tr>
<tr>
<td>Pulse rate (beats/min)</td>
<td>82.72±3.79</td>
</tr>
</tbody>
</table>

Table 2: Maternal cardiorespiratory parameters and fetal heart rate

<table>
<thead>
<tr>
<th>Maternal Pulse rate</th>
<th>Primigravida</th>
<th>Multigravida</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>At the time of injection</td>
<td>85.62±27</td>
<td>83.79±22</td>
<td>0.99</td>
</tr>
<tr>
<td>30 minutes after injection</td>
<td>88.23±45</td>
<td>84. 98±53</td>
<td></td>
</tr>
<tr>
<td>After delivery</td>
<td>84.95±67</td>
<td>84.13±78</td>
<td></td>
</tr>
</tbody>
</table>
Maternal Respiration
At the time of injection 18.25±3.4 18.16±4.5 0.99
30 minutes after injection 18.64±2.6 18.98±6.6
After delivery 18.33±2.2 17.98±2.3

Maternal Blood Pressure
At the time of injection Systolic 120.25±4.5 120.63±3.7
Diastolic 80.45±8.7 81.55±9.4
30 minutes after injection Systolic 125.20±9.7 125.83±7.6
Diastolic 83.5±5.8 82.15±6.3
After delivery Systolic 118.55±7.8 119.72±3.3
Diastolic 80.76±8.9 81.14±5.6

Fetal heart rate
At onset of labor 142.1±4.6 141.77±5.7 0.99
At the time of Inj 141.95±7.5 142.65±8.9
30 mins after Inj 141.23±6.7 141.85±8.4

The P value calculated by Chi-Square test to the above variables shown statistically insignificant. Indicating that maternal cardiorespiratory parameters and FHR are not different significantly among primigravida and multigravida.

Table 3: Pain relief score (Oxford score):

<table>
<thead>
<tr>
<th>Parity</th>
<th>Tramadol Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Score - 3</td>
</tr>
<tr>
<td>Primigravida</td>
<td>22 (44%)</td>
</tr>
<tr>
<td>Multigravida</td>
<td>11 (22%)</td>
</tr>
</tbody>
</table>

The P value is 0.033 which is statistically significant calculated by Chi-Square.

Pain relief is more in multigravida when compared to primigravida. Score -3 indicates moderate and score-4 indicates good. Onset of analgesia was within 15mins.

Table 4: Mode of delivery

<table>
<thead>
<tr>
<th>S.No</th>
<th>Parity</th>
<th>No. of Patients</th>
<th>Spontaneous Vaginal Delivery</th>
<th>Forceps Delivery</th>
<th>LSCS abdominal Delivery</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Primigravida</td>
<td>50</td>
<td>39 (78%)</td>
<td>3 (6%)</td>
<td>8 (16%)</td>
</tr>
<tr>
<td>2.</td>
<td>Multigravida</td>
<td>50</td>
<td>47 (94%)</td>
<td>1 (2%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>100</td>
<td>86</td>
<td>4</td>
<td>10</td>
</tr>
</tbody>
</table>

The P value is 0.079 calculated using Chi-Square test which is very highly significant.

Table 5: Duration of labor in hours:minutes

<table>
<thead>
<tr>
<th>Parity</th>
<th>Tramadol Injection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Total</td>
</tr>
<tr>
<td>Primigravida</td>
<td>14.91</td>
</tr>
<tr>
<td>Multigravida</td>
<td>13.04</td>
</tr>
</tbody>
</table>

All Stages of labor duration decreased with tramadol i.m inj. Multigravida has lesser duration of labor when compared to primigravida. This is statistically insignificant which means minimal difference between variables.
Table 6: Number of Top-Ups required:

<table>
<thead>
<tr>
<th>No. of Top-ups</th>
<th>Primigravida</th>
<th>Multigravida</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>14 (28%)</td>
<td>31 (62%)</td>
</tr>
<tr>
<td>2.</td>
<td>36 (72%)</td>
<td>19 (38%)</td>
</tr>
</tbody>
</table>

The P value is 0.0013 calculated using Chi-square test which is very high statistically significant. Tramadol top up requirement is more in primigravida when compared to multigravida, which is significant.

Side effects of tramadol among primi and multigravida is depicted in (Fig. 1). Side effects in primigravida and multigravida are almost same. Palpitation and drowsiness are more in primigravida when compared to multigravida.

![Figure 1: Side effects of Tramadol](image)

**DISCUSSION**

Dilatation stage in labor if prolonged may lead to exhaustion and psychological burden to mother. The labor pain rises serum catecholamine’s which can cause fetal tachycardia, bradycardia or dysfunctional uterine action. An ideal analgesic agent should therefore take into consideration, maternal wishes and preferences, available expertise, support staff and facilities. The present study was undertaken to evaluate the efficacy and safety of tramadol hydrochloride i.m injection as labor analgesia among Primigravida and Multigravida.

Majority of the women were in the age group of 21 to 26 years. This correlates well with other studies done earlier by different workers [7-9]. As far as parity was concerned, equal number of cases were taken in each group (50). There was no major difference in pain relief in different age groups, irrespective of parity.

In this study the maternal adverse effects were minimal and there is no much difference between primigravida and multigravida (Table 2). This is in line with other studies by Meena et al [10], Prasertsawat et al [11] and suvonnakote et al [12].

No significant changes in the fetal heart rate pattern were noted among Primigravida and Multigravida after receiving i.m tramadol inj. Keskin et al [13] and Li and Weng [8] also did not observe any change in fetal heart rate.

In the present study pain relief score is better in multigravida (78%) than in primigravida (56%). The duration of analgesia was 3.78 hrs in primi and 4 hrs in multigravida. Li and Weng [8] observed that effective pain relief with tramadol was seen in 67%.Bajaj et al [9] noted that mean pain relief was 38.92% with tramadol. Nulliparous women are more likely to experience severe pain than multiparous women as reported by Melzaek [14].

Total duration of labor in multigravida (13.04) is lesser than primigravida (14.91) Tramadol reduces the duration of labor in...
all stages both in multigravida and primigravida in this study. Anahitapandole et al[15] also reported that 1st and 2nd stage of labor duration decreases with tramadol in both primigravida and multigravida, as lesser duration in multigravida than primigravida. While, other studies like Milwidsky et al[16], Husslein et al[17] and Viegas et al[18] observed that decrease in duration of labor with tramadol.

In this study multigravida underwent more number of spontaneous vaginal deliveries than primigravida and tramadol has reduced the LSCS deliveries. Sarkar et al[19] showed that the caesarean delivery rate was reduced with tramadol (17%).

Tramadol top up requirement is more in primigravida when compared to multigravida, which is statistically significant.

Side effects in primigravida and multigravida are almost same. No side effects are seen in 86% primigravida and 90% multigravida. Palpitation and drowsiness are more in primigravida when compared to multigravida.

CONCLUSION

The outcome of the study reveals that tramadol hydrochloride is safe and effective labor analgesia for both primigravida and multigravida. Tramadol is more effective in multigravida than in primigravida. As labor pain is one of the cause for increase in morbidity of mother, by administering tramadol can make labor as a pleasurable moment to mother.

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REFERENCES