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A study to compare the maternal and fetal effects with the use of tramadol as an analgesic during labour

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Abstract
Perception of pain during the first stage of labour begins with nociceptive stimuli arising in the mechanical and chemoreceptors in the uterus and cervix. High threshold mechanoreceptors get stimulated due to intense pressure generated during contractions of the uterus.[22]Myocellular injury due to repeated contractions in later stages, release bradykinin, histamine, serotonin, acetylcholine and potassium ions which activate chemical nociceptors. 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. Among the intervention group 94.28% (33 babies) had no depression, 5.7% (2 babies) had mild depression and none of the babies had severe depression at 1 minute. In the control group 88.5% (31 babies) had no depression, 11.4% (4 babies) had mild depression and none of the babies had severe depression at 1 minute. p> 0.05, statistically not significant.

Keywords: Maternal and fetal effects, tramadol, analgesic during labour

1. Introduction
Labour is characterized by regular, painful uterine contractions that increase in frequency and intensity and are associated with progressive cervical effacement and dilatation. Labour has been divided into three stages. The first stage occurs from onset of true labour pain to 10cm. cervical dilatation. It can be divided into latent and active phase. The latent phase can last up to 8 hrs, without the need of intervention, while the active phase is associated with a faster rate of cervical dilatation and usually begins at 3-4cm dilatation and the duration varies from 2 to 6hrs. The second stage occurs from full cervical dilatation (10cm.) to the delivery of the baby. Normally the second stage lasts for 2 hrs (3hrs. with regional anaesthesia) in a primigravida and 1 hr (2hrs. with regional anaesthesia) in a multigravida. The third stage starts after the delivery of the baby to separation and expulsion of the placenta and membranes [1].
Perception of pain during the first stage of labour begins with nociceptive stimuli arising in the mechanical and chemoreceptors in the uterus and cervix. High threshold mechanoreceptors get stimulated due to intense pressure generated during contractions of the uterus. Myocellular injury due to repeated contractions in later stages, release bradykinin, histamine, serotonin, acetylcholine and potassium ions which activate chemical nociceptors [2].
Pain during the first stage of labour is due to uterine contractions and stretching of the cervix. It is cramping and visceral in nature, diffuse and poorly localized. Sensations are carried through Aδ and C primary afferent fibers which travel with sympathetic nerves sequentially through the inferior, middle and superior hypogastric plexus, the lumbar and lower thoracic sympathetic chain and end in rami communicates associated with T-10-L1 spinal nerves. It is predominantly carried by the C fibers.
Tramadol is a synthetic 4-phenyl-piperidine analogue of codeine. Tramadol hydrochloride is a centrally acting analgesic drug, with a low affinity for opioid receptors, is a racemic mixture of 2enantiomers, (+) tramadaol and (-) tramadol both of which contribute to analgesic activity via different mechanisms and has chemical structure (1 RS, 2 RS)-2- [(dimethylamino) methyl]-1-(3-methoxyphenyl)- cyclohexanol hydrochloride [3].
The analgesic potency of tramadol is about 10% of that of morphine following parenteral administration. Tramadol provides postoperative pain relief comparable with that of pethidine, and the analgesic efficacy of tramadol can further be improved by combination with a non-opioid analgesic.

Tramadol may prove particularly useful in patients with a risk of poor cardiopulmonary function, after surgery of the thorax or upper abdomen and when non-opioid analgesics are contraindicated. Tramadol can be administered concomitantly with other analgesics, particularly those with peripheral action [4].

Tramadol should not be administered to patients receiving monoamine oxidase inhibitors, and administration with tricyclic antidepressant drugs should also be avoided. Tramadol can be administered concomitantly with other analgesics, particularly those with peripheral action, while drugs that depress CNS function may enhance the sedative effect of tramadol (alcohol, hypnotics) [4]. When combined with tranquilizers, it has a favourable effect on pain sensation.

It has also got interactions with coumadin anticoagulants. Ondansetron may interfere with the analgesic component of tramadol that is due to its effects on the reuptake and release of 5-hydroxytryptamine [5].

Tramadol is a central acting analgesic which has been shown to be effective and well tolerated, and likely to be of value for treating several pain conditions (step II of the World Health Organization ladder) where treatment with strong opioids is not required [6].

Methodology

Study design: Interventional Study

Study setting: Department of Obstetrics and Gynaecology, Medical College & Research Foundation.

Study population:

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.

Exclusion Criteria

1. Patients with history of hypersensitivity to the drug, respiratory disease.
2. Hypertension
3. Heart disease
4. Diabetes
5. Epilepsy
6. Malpresentation
7. Previous Caesarean Section
8. Psychiatric disorders were excluded from the study.

Inclusion Criteria

1. Primi/multigravidae between 18-35 years of age, without any of the above diseases
2. Term pregnancies (37-42wks) with vertex presentation
3. With good fetal well being
4. Without any obstetric complication
5. Without Cephalopelvic Disproportion (CPD) and vaginal delivery is anticipated.

Results

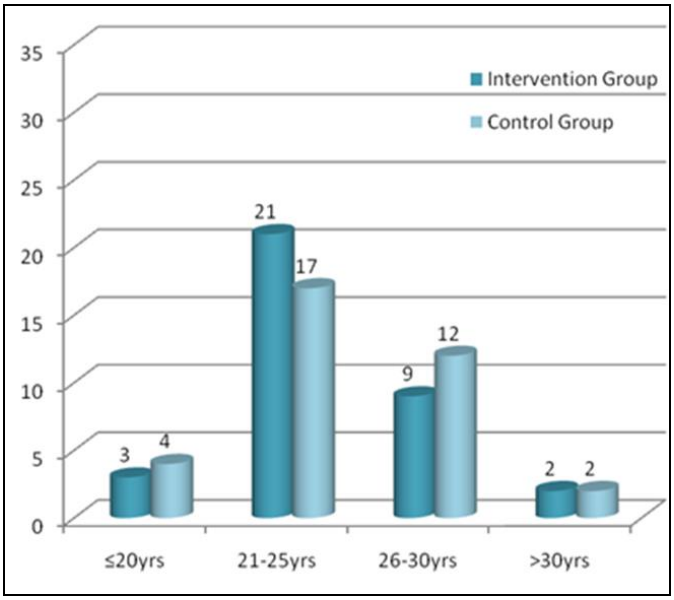

Fig 1: Age Distribution

Figure-1 shows the age distribution of patients, patients included in this study were between 18-35 years in both the intervention and control group. In the both the groups, maximum number of patients were between 21-25 years. There is no significant difference in the age distribution among the study participants. Fishers exact test showed p-value >0.05 → statistically not significant. Table-1 shows the distribution of parity in the Intervention and Control groups.

Table 1: Distribution of Parity

Parity	Intervention Group	Control Group
Primigravida	18	17
Multigravida	17	18

Pearson Chi-Square =0.057 and p= 0.811; Not significant

Primigravidae and multigravidae were chosen for the study. The distribution of parity was almost equal among the intervention and control groups.

A few of the minor side effects of the drug like vomiting, nausea, dizziness, sedation was found in the study group, whereas in control group there was no such problem.

Table 2: Maternal Side Effects Following Tramadol

Side Effects	Tramadol Group
No side effects	28
Nausea	2
Vomiting	2
dizziness	2
sedation	1

Table 3: Represents the neonatal Apgar score at 1 & 5 minutes respectively

Apgar Score	Study group		Control group	
	1'	5'	1'	5'
Severe depression	0	0	0	0
Mild depression	2	0	4	0
No depression	33	35	31	35

Among the intervention group 94.28% (33 babies) had no depression, 5.7% (2 babies) had mild depression and none of the babies had severe depression at 1 minute. In the control group 88.5% (31 babies) had no depression, 11.4% (4 babies) had mild depression and none of the babies had severe depression at 1 minute. $p > 0.05$, statistically not significant.

All the babies in both intervention and control groups had no depression at 5 minutes.

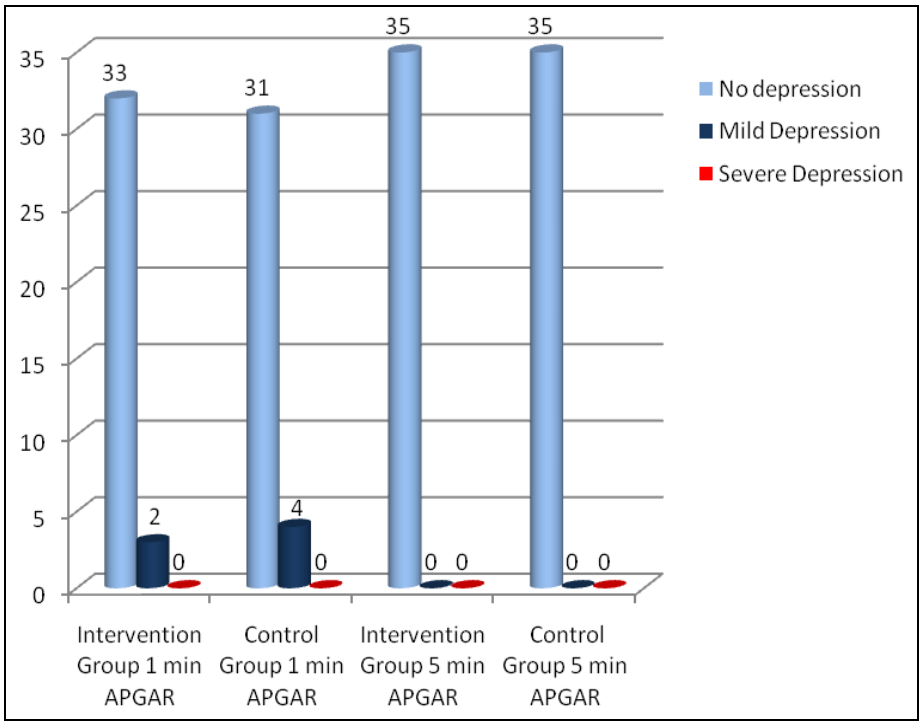

Fig 2: Neonatal Apgar at 1 min. and 5 min. in the Intervention and Control Groups

Table 4: Neonatal Morbidity

Neonatal Morbidity	Intervention Group	Control Group
Fair	33	31
Mild birth asphyxia	1	3
Meconium aspiration	1	1

In the intervention group, one baby had mild birth asphyxia with one loop of tight cord around the neck, with an Apgar score of 6 at 1min. and 7 at 5min. Another baby had meconium aspiration, delivered by emergency LSCS due to fetal distress. This baby had Apgar of 6 & 8 respectively at 1min. & 5min. In the control group 3 babies had mild birth asphyxia. One had two loops of cord around the neck; this baby had an Apgar of 6 & 7 at 1 &5 minutes respectively. Another baby had shoulder dystocia, was delivered by Mc'Robert's Manoeuvre along with suprapubic pressure, this baby had an Apgar of 5 & 7 at 1 & 5 minutes respectively. Another baby with mild birth asphyxia was the one delivered by LSCS indication being fetal distress with thin meconium stained liquor, Apgar was 6 & 8 at 1' & 5' respectively. All 3 babies were admitted to NICU for observation for 1 day. In the control group another baby had meconium aspiration with an Apgar of 6 & 7 at 1 and 5min. respectively. However, in both the study and the control groups, there was no severe neonatal morbidity.

Discussion

Only a few of the minor side effects of the drug like nausea, vomiting, dizziness, sedation were found in the intervention group, whereas in control group there was no such problem. Nausea was seen in 5%, vomiting in 6%, dizziness in 6%, sedation in 3% among the Tramadol group. There was no case of severe maternal morbidity in both the intervention and control group. In the present study there was no significant change in the vital parameters like maternal pulse rate, respiratory rate, and blood pressure after administration of Tramadol. Also there was no difference in the foetal heart rate following administration of Tramadol. In a study conducted by Nagaria T, Acharya J[7] the authors reported similar results in their study. In the study conducted by Bajaj *et al*, [8] pulse rate and blood pressure were found to be decreased, but it was statistically insignificant. Thakur R, Patidar Rekha [9] noted the maternal side effects with the tramadol group in the form of nausea (7%), vomiting (3%), drowsiness (2%) in their study. Suvonnakote *et al*. [10] and Prasertsawat *et al*. [11] reported minimal side effects in women receiving Tramadol.

Among the intervention group 94.28% (33 babies) had no depression with a 1 minute Apgar of ≥ 7. 5.7% (2 babies) had mild depression with 1 minute Apgar of < 7 and none of the babies had severe depression at 1 minute. The cause of mild depression in 2 babies was mild birth asphyxia with one loop of tight cord around the neck (one of them delivered by emergency LSCS due to fetal distress with thin meconium stained liquor while the other one was delivered by vaginal delivery). In the control group 88.5% (31 babies) had no depression with Apgar of ≥ 7, 11.4% (4 babies) had mild depression with Apgar of < 7 and none of the babies had severe depression at 1 minute. $p > 0.05$; statistically not significant.

All the babies (100%) in both the intervention and control groups had no depression at 5 minutes (Apgar >7). Hence, in the present study there is no statistically significant difference in the neonatal Apgar score at 1 and 5 min among the babies of the study participants. Nagaria T, Acharya J [7], reported the 1 minute Apgar score of > 7 in 98% of babies in the Tramadol group. Sudha P *et al*. [12] reported 96% babies of Tramadol group with Apgar >7 at 1 minute. Bajaj *et al*. [8] reported an Apgar score of >8 at 1 minute in all neonates of the Tramadol group. In

all these studies the 5 minute Apgar score was >7 in 100% of the neonates. The neonatal Apgar scores of ≥ 7 at 1 and 5 minutes respectively in the Intervention group in the studies conducted by Nagaria T, Acharya J [7], Sudha P *et al*. [12], Bajaj *et al*. [8] and the present study.

In the intervention group, one baby had mild birth asphyxia with one loop of tight cord around the neck; the baby had an Apgar of 6 at 1min. and 7 at 5min. This baby had to be resuscitated and shifted to NICU (Neonatal Intensive Care Unit), the baby was given oxygen, kept under observation and returned to the mother on the 2nd post natal day. There was another baby with meconium aspiration, delivered by emergency LSCS due to fetal distress. Intraaoperative findings were-1 loop of tight cord around the baby's neck, with thin meconium stained liquor. This baby had Apgar of 6 & 8 respectively at 1min. & 5min.The baby was given a stomach wash and observed in NICU for a day and then shifted to mother's side on her 1st post operative day.

In the control group 3 babies had mild birth asphyxia. One had two loops of cord around the neck; this baby had an Apgar of 6 & 7 at 1 &5 minutes respectively. Second baby had shoulder dystocia and was delivered by Mc'Robert's Manoeuvre along with suprapubic pressure, this baby had an Apgar of 5 & 7 at 1 & 5 minutes respectively. The third baby with mild birth asphyxia was the one delivered by LSCS indication being fetal distress with thin meconium stained liquor, Apgar was 6 & 8 at 1' & 5' respectively. All 3 babies were admitted to NICU for observation for 1 day. In the control group another baby had meconium aspiration, Apgar 6 & 7 at 1' and 5', was managed in NICU and shifted to the mother on 2nd postnatal day. However, in both the study and the control groups, there was no severe neonatal morbidity.

Conclusion

- Tramadol causes good tolerability profile and apparent lack of abuse and dependence, and minimal risk of respiratory depression in both mother and baby.
- Tramadol caused only minor side effects in few of the study participants.
- No significant maternal and fetal complications were encountered in this study. Haemodynamic and respiratory parameters were not significantly impaired in the mother.

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