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Research Article

A PROSPECTIVE STUDY OF EFFECT OF INTRAMUSCULAR TRAMADOL IN LABOUR ANALGESIA

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ABSTRACT
The aims and objectives of this study was to evaluate the effect of intramuscular "Tramadol hydrochloride" in labour analgesia in terms of Qualitative estimation of pain relief, Duration of first stage of labour and second stage of labour, Incidence of operative intervention and its effect on mode of delivery, Perinatal outcome, Side effects of drug. This was a prospective study conducted in tertiary hospital where 40 patients in each –study and control group were selected. In the study group injection tramadol was given intramuscular and in control group placebo injection of distilled water was given. All the patients were selected from active labour and were monitored throughout for the vital parameters, progress of labour by partographic chart, mode of delivery, newborn apgar score and perinatal outcome and any side effect of the drug.

Keywords: *Labour Analgesia, Tramadol*

INTRODUCTION
Memories of pain fade consistently as shown in some of studies. Morgan (1982) highlighted that more than 90% of the mothers had forgotten labor pain severity 3 months later, when they viewed the experience with satisfaction. In one of the Swedish study (1976), even when questioned one or two days post-partum 35% of women recollected intolerable pain, 37% of severe and 28% moderate degree of pain. In Finnish survey (1994) of 833 parturients 4% reported only mild pain and after delivery 60% of them said that pain was severe and intolerable. According to McGill pain Questionnaire Melzack *et al.*, (1981) in Montrea, Canada, found that labour pain usually rated a high score particularly primiparae, those women with history of dysmenorrhoea and those of low socioeconomic status.
If pain is so quickly forgotten then why use artificial means to treat to it?
The reason is:
1. Though pain may be quickly forgotten this does not make it any more tolerable at the time. It is to therefore only humane to attempt to relieve it.
2. Though anxiety may be believed to exacerbate pain, relieving pain dramatically reduce mother's anxiety.
3. Pain of labor represents severe physiological stress which can result in maternal metabolic acidosis and hormone imbalance including catecholamine release. Stimulation of α-receptors causes vasoconstriction which may affect the maternal blood supply to the placenta while β-stimulation may prolong labour. This causes adverse effects on mother as well as baby.
So then it then becomes appropriate to offer the women relief from pain. In past two decades anaesthesia for obstetrics has achieved distinction of a scientific and profession of subspeciality. The practice of obstetrics analgesia has altered greatly in recent years and many factors are responsible for this. Such as introduction of newer drugs and techniques of drug delivery, increasing rate of operative delivery and the more accurate assessment of feta well being. Thus the role of labour analgesia in modern obstetrics is invaluable.

MATERIALS AND METHODS
This prospective study was carried out in 80 patients of age group of 18-35 years in the department of obstetrics and gynaecology at our hospital from June 2014 to June 2015. This if a tertiary referral hospital which has approximately 6000 deliveries per year out of which more than 50% are referred cases. This

study was carried out in pregnant women of gestational age 35 to 42weeks who were in active labour. Active labour was defined as the dilatation of the cervix more than 3 cms with uterine contractions one every two to three minutes and lasting for 30 seconds and more. Prper prior counseling and thorough consent was taken. Proper assessment of the patient was done by thorough history taking and examination.

Exclusion Criteria

Patient not willing for analgesia were excluded from this study. Patients having Hb<8 gm%, h/o respiratory disease, hypertension, epilepsy, psychiatric disorder, drug reaction, patients with –fetal distress, thick meconium stain liquor , nonreactive NST on admission, intrauterine fetal death, cephalopelvic disproportion were all excluded from this study.

Investigation as Hb, blood group, VDRL, HIV, HbsAg were checked

Technique

In group I of 40 patient's injection of tramadol 100mg was given intramuscular after the start of active labour pains. In group II was control group where placebo injection of two ml distilled water intravenous was given as labour analgesia. In all patients following things were monitored.

1. Hemodynamic monitoring-Vital parameters such as maternal pulse, respiratory rate, blood pressure were monitored half hourly.
2. Progress of labour-Uterine activity and fetal heart rate was monitored every half hourly. Partograph was used to monitor progress of labour.
3. Analgesic effects-The percentage of pain relief by score was noted before giving the drug and assessed at 1hr, 2hrs and 4hrs. Average pain relief percentage calculated be verbal rating method and expressed as

Grade	**Percentage**	
0	0%	No pain relief
1	<25%	Unsatisfactory pain relief
2	25-49%	Satisfactory pain relief
3	50-75%	Good pain relief
4	>75%	Excellent pain relief

More than 50% pain relief is considered as significant

4. Duration of labour-

1st stage of labour- from onset of active labour to full dilation of cervix. Average duration was taken as 8hrs in primipara and 5 hrs in multipara.

2nd stage of labour- from full dilatation of cervix to delivery of baby. Avereage duration ws taken as 50 mins in primipara and 20 mins in multipara.

3rd stage of labour-from delivery of baby to delivery of placenta.

All patients were observed for 2 hrs for any postpartum complications

5. Mode of delivery ---spontaneous vaginal delivery

Outlet forceps applications

Caesarean section

6. APGAR SCORE- It was noted in babies of both groups at interval of 1 min and 5 mins after the birth. All the deliveries were attended by neonatal housesurgeon and the neonatal side effects related to the drugs were noted. Accordingly babies were transferred to mother, high dependency unit (HDU) and neonatal intensive care unit (NICU) and reassessed by their seniors.
7. Side effects

Maternal side effects such as altered consciousness, sedative effects, vomiting, hypotension and fetal such ad fetal distress were noted. Babies were followed up till the date of discharge.

RESULTS AND DISCUSSION

Results

AGE –The age of the patients varied between 18-34 years. 82.5% of the total patients in the 'tramadol' group belonged to age group of 18-25 years as compared to 85% in the' control' group. 7.5% of the total patients in the' tramadol' group and 12.5% of total cases from the 'control' group belonged to age group of 26-29 years of age. Average age of the cases in 'tramadol' and 'control' group was 21.98 and 21.68 respectively

PARITY- 62.5 to 65% of total cases in both 'tramadol' and'control' groups were primipara and 35 to 37.5% were multipara respectively.

MODE OF DELIVERIES IN BOTH THE GROUPS-There was no significant difference found regarding mode of deliveries in both groups. 37 (92.5%) of total deliveries in both groups had normal vaginal delivery. Incidence of caesarean sections was slightly higher in control group but not significant. Two patients in tramadol group required caesarean section while three patients from control group required caesarean section. Indications of caesarean sections in tramadol group were deep transverse arrest and non progress of labour in 1st stage while in control group fetal distress in two patients and deep transverse arrest in one. Only one patient from tramadol group required forceps delivery.

Duration of Stage of Labour

Table 1: Duration of Stage of Labour

GROUPS	Primi		Multi	
	I st stage (hrs)	2nd stage(mins)	1st stage (hrs)	2nd stage (mins)
Tramadol	5.99 ±1.30	29.80±16.8	3.52±1.25	15.61±9.94
Control	6.49±1.39	28.56±19.23	4.06±1.23	12.06±6.18

Average duration of 1st stage of labour was slightly less in tramadol group and 2nd stage was slightly less in control group but difference was not statistically significant.

Fetal Apgar Score

Table 2: Comparison of fetal apgar score in both study groups

Apgar score	Tramadol		Control	
	No	%	No	%
At 1 mins				
7-9	37	92.5%	34	88.5%
5-6	03	7.5%	03	7.5%
<4	-	-	03	7.5%
At 5 mins				
7-9	40	100	39	97.5%
5-6	-	-	-	--
<4	-	-	01	2.5%

**P>0.05 Not significant*

In tramadol group 3 babies and in control group 6 babies required active resuscitation in the form of nasal oxygen and suction at birth. Only one baby in control group required intubation and was transferred to NICU. This baby incidentally had tight cord loops around neck. Baby recovered within 7 days. Hence the difference was not statistically significant.

Table 3: Comparison of amount of pain relief between both groups

	Tramadol						Control					
% of pain relief	**1hr**		**2hr**		**4hr**		**1hr**		**2hr**		**4hr**	
	No	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**	**No**	**%**
0	2	5	2	5	7	17.5	2	5	4	10	16	40
<25	4	10	1	2.5	8	20	4	10	7	17.5	18	45
25-49	12	30	6	15	21	52.5	27	67.5	18	45	5	12.5
50-75	19	47.5	26	65	3	7.5	7	17.5	9	2.5	-	-
>75	3	7.5	5	12.5	1	2.5	-	-	2	5	-	-
Total	40		40		40		40		40		40	

**P<0.01 significant*

If patient has more than 50% relief, we have considered that is a significant pain relief. Our study had shown that maximum effect of tramadol was at 2 hrs, gradually reducing at the end of 4 hrs. Table shows that in tramadol group 55% of total cases had more than 50% relief after 1 hr where as only 17.5% of total cases had more than 50% pain relief in the control group. While 77.5% of cases in tramadol group had significant pain relief after 2 hrs as compared to only 27.5% in the control group. The difference was statistically significant P<0.01.

Side Effects

In our study only 15% (6cases) of cases from tramadol group had sedation and only one patient had vomiting, that was not significant and was not affecting the progress of vital parameters.

Discussion

Tramadol hydrochloride is a synthetic 4 phenylpiperidine analogue of codeine. Molecular formula is C16 H25 O2NHC. Tramadol hydrochloride is a modestly potent opioid analgesic which interacts with mu, delta, kappa, opioid receptors when it exhibits purely agonists effects. Tramadol is effective in relieving moderate to severe pain associated with surgical procedures, labour neuralgias, cancer and following trauma. It does not exert inhibitory effects on the respiratory centre hence used for obstetric analgesia. It can be administered orally, reactally, intramuscularly, intravenously, epidurally and intrathecally. Tramadol in solution for injection contains only tramadol hydrochloride 50mg/ml in aqueous sodium acetate buffered solution without any preservatives the PH is 6-6.8. The dose for parenteral administration is 1.5-2 mg/kg of body weight. In our study we evaluated the effects if tramadol in carefully selected 40 patients. We observed the different parameters such as duration of all stages of labour, progress of labour, fetal apgar score, mode of delivery in the tramadol group. We compared all the parameters with the control group where placebo injection was given. Demographic characters were comparable in both the groups. We observed that the drug lessens the average duration of labour. This difference however was not statistically significant. Viegas *et al.,* (1993) in his study on tramadol in labour pain in primigravida patients showed that tramadol 100 mg is as effective as pethidine 75mg bur has superior safety profile mainly considering respiratory distress. In our study we have compared it with control group (placebo). In our study there was no adverse fetal outcome in both the groups. Sarkar *et al.,* (1997) demonstrated that in the tramadol group fetal distress was three times less compared to the pethidine group. He also showed that duration of labour was shortened in tramadol group compared to pethidine.

In our study we found that significant pain relief was observed in 55% of total cases at 1 hr and 77.5% of total cases at 2 hrs in the tramodol group. This difference was statistically significant (P<0.01) compared to control group. Husslein *et al.,* (1987) study suggested the tramadol has an analgesic effect similar to that of pethidine but with lesser side effects than pethidine. Majority of studies have compared tramadol with pethidine for labour analgesia. Viegas *et al.,* (1993) in his study also showed that the effectiveness of tramadol as a labour analgesic is the same as that of pethidine but with fewer side effects.

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. So, why not give the woman in labour the benefit of labour analgesia?

Our study suggests 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 fetus. It does not prolong average duration of labour. It has fewer side effects.

Though it is said that memories of pain fade consistently, this does not make it any more tolerable at the time. It is therefore only humane to attempt to relieve it and make labour more memorable for the woman.

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