Comparative Study Of Tramadol Hydrochloride And Drotavarine Hydrochloride On Cervical Dilatation In Active Labour

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Abstract: **Purpose:** Prolong labour contributes to increased perinatal and maternal morbidity. Inhibitory impulses in the form of spasm often impair the dilatation of cervix and prolong the duration of labour. This study was undertaken to compare the effect of Tramadol Hydrochloride And Drotavarine Hydrochloride on duration of labour and rate of cervical dilatation and compare it with control group. **Method**-300 patients were taken up for study. Of these 300 patients both primipara & multipara were included. In the multipara, only second para (OH=1001) were included to ensure comparability. 100 patients served as control. Majority of patients belong to age group 21-25 in all three groups. This is a Hospital based randomized study to evaluate the acceleration effect of Tramadol and Drotaverine on dilatation of cervix in both primigravida & multigravida with additional analgesic effect of Tramadol and compare it with control group,to note the time interval between injection of Tramadol and Drotaverine & delivery and compare it with control group,to determine deleterious effects if any of drugs affecting either fetus or mother in primi & multi patients with no high risk factors. **Results** - Both Tramadol and Drotaverine reduce the duration of first stage, less operative interference was required into two study groups in comparison to control group, in both primpara and multi para patients. Results of both drug are comparative.Among primiparous patients, two each of Tramadol and Drotaverine group had forcep delivery and two patients of Tramadol group had undergone lower segment cesarean section.Among multiparous patients, four patients of Drotaverine group delivered by lower segment cesarean section. Both the drugs had no significant action on the uterine contraction .Both the drug reduce the duration of active phase of labour and there who significant increase of rate of cervical dilatation in Tramadol and Drotaverine group compared to control group.Both the drugs had no significant effect on duration of second and third stage of labour. There was no significant difference in the APGAR score of babies delivered with the aid of Tramadol and Drotaverine as compared to control group.Both the drugs had minimal side effects and complications. **Conclusion**: It can be opined that Tramadol hydrochloride is a good cervical dilator and its effects is comparable to Drotaverine hydrochloride but due to its added analgesic effects, Tramadol can be preferred over Drotaverine hydrochloride and other cervical dilators for augmentation of labour.But further studies are required to have the data sufficient enough to establish the drug as better cervical dilator than Drotaverine.

Keywords: Tramadol hydrochloride, Drotaverine hydrochloride, Cervical dilatation; Active phase; Delivery.

INTRODUCTION

A labour which is unduly prolonged is likely to give rise to one or more of 3 types of distress namely maternal, fetal or obstetrician. Of the three the last may be most dangerous! Ian Donald. Prolonged & painful labour presents a picture of mental anguish & physical morbidity. It constitute danger to the survival & subsequent neurological development of infant. Prolonged labour can lead to increased maternal and neonatal mortality and morbidity due to increased risks of maternal exhaustion, postpartum haemorrhage and sepsis, fetal distress and asphyxia and requires early detection and appropriate clinical response. The causes of prolonged labour relate to maternal age, induction of labour, premature rupture of membranes, early admission to the labour ward, epidural analgesia and high levels of maternal stress hormones, but are unknown in most cases (Dencker 2009)[1]. The risks for complications of prolonged labour are much greater in poor resource settings (Neilson 2003)[2].

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It is difficult to give a clear definition for prolonged labour. In practice, as recommended by the WHO maternal health and safe motherhood programme (WHO 1994)[3], a woman should be transferred to a higher level of care if her rate of cervical dilatation (according to the partogram) becomes less than 1 cm/hour, and requires prompt, appropriate management if it is less than 1 cm in four hours (Lavender 2009)[4]. In addition, a recent review to determine the "slowest-yet-normal" dilatation rate amongst primigravid women (Neal 2010)[5], determined that this dilatation rate approximates 0.5 cm/hour and that expectations of a faster dilatation rate (1 cm/hour) can lead to unnecessary interventions aiming to accelerate labour. The concept of "active management of labour" (O'Driscoll 1973)[6] was developed to assure a woman that her labour would not exceed 12 hours. Anything beyond that constituted prolonged labour. This package of care includes accurate and early diagnosis of the first stage of labour, early artificial rupture of membranes, ongoing support of the woman in labour by a professional caregiver and augmentation of labour with oxytocin (O'Driscoll 1994)[7]. Active management of labour versus physiological, expectant management, has shown to decrease the occurrence of prolonged labour (more than 12 hours). A Cochrane review found that active management significantly shortened the duration of labour by 1.27 hours, while the first stage of labour was significantly reduced by 1.56 hours. It also showed a small reduction in the rate of caesarean sections. There was no significant difference in maternal and neonatal morbidity (Brown 2008)[8]. Wei 2009[9] showed that early intervention with amniotomy and oxytocin augmentation, as a preventative strategy with mild delays in progress, leads to a reduction of 1.16 hours in the

duration of labour. Various tranquilizers, analgesics and sedatives used to relieve labour pains can lead to fetus. Other commonly used used to drugs in labour like oxytocin and prostaglandins, although reduce duration of labour, they do not reduce the suffering caused by labour pains. For the mother it provides relief from pain, controls alteration in circulation, ventilation and undue muscular efforts. For the fetus, shorter and less traumatic labor, protection against hypoxia, fetal depression at birth, protection against needless instrumental delivery. To the obstetrician, it provides a better control over events emerging during the course of labor and ensures optimum conditions to prevail at the time of child birth. 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.[10] Tramadol hydrochloride is centrally acting analgesic which has got both opioid and non-opioid mechanism of action. It also causes cervical dilatation. It also causes cervical dilatation. It activates only 30% of opioid receptors (Kappa and μ). It inhibits noradrenergic uptake and stimulates serotonin release. These are no adverse effect on GIT, respiratory, cardiovascular and central nervous system.Drotin is musculotropic drug acting directly on smooth muscle cells. It has no central action. It produces smooth muscles cell relaxation. Tramadol has been found to be an effective analgesia in labor without having a deleterious effect on the mother and the fetus. The incorporation of partogram into the protocol helped to eliminate the ill effects of prolonged labors, prompted earlier recognition of dystocia and implementation of measures at the same time. Drug Assisted Labour leads to shorter labors; analgesia is quite effective and side effects of drugs are minimal and safe for the fetus as well; labor is cherished with pleasure and childbirth becomes a joyous event for the mother.[11] In the present study TRAMADOL is evaluated for same purpose which is compared with DROTIN which is a cervical dilator.

AIMS AND OBJECTIVES

1. To evaluate the acceleration effect of Tramadol and Drotaverine on dilatation of cervix in both primigravida & multigravida with additional analgesic effect of Tramadol and compare it with control group.
2. To note the time interval between injection of Tramadol and Drotaverine & delivery and compare it with control group.
3. To determine deleterious effects if any of drugs affecting either fetus or mother.

Materials and Methods:

Source of Data

This is a hospital based study. Primi gravidae & Multigravidae at term, with no high risk factors who are in active phase of labor are to be included in the study.

Method of the Collection of the Data

Study Design::1 year randomised control study
Sample size: 300 Patients
Place: Department of Obstetrics and Gynaecology, Kasturba Hospital, BHEL, Bhopal
Duration: 2006-2007

Method: This is a Hospital based randomized study to evaluate the acceleration effect of Tramadol and Drotaverine on dilatation of cervix in both primigravida & multigravida with additional analgesic effect of Tramadol and compare it with control group,to note the time interval between injection of Tramadol and Drotaverine & delivery and compare it with control group,to determine deleterious effects if any of drugs affecting either fetus or mother in primi & multi patients with no high risk factors. Three Hundred women at 37 to 41 weeks gestational age with cephalic presentation and in active phase of labor with cervical dilatation of 3-4 cm and good cervical effacement, should be included in the study. None should have clinical evidence of cephalopelvic disproportion, or history of medical disorders like Hypertension, Cardiac disease, Bronchial asthma, Diabetes, Jaundice.

Inclusion Criteria:

- Primipara and multipara
- Full term singleton pregnancy with vertex presentation.
- No chronic or pregnancy induced illness.

Exclusion Criteria:

1. Scarred uterus
2. Fetal demise
3. Multiple pregnancy
4. Malpresentations
5. Cephalopelvic disproportion
6. Medical complication like heart disease, diabetes, asthma, myasthenia gravis, glaucoma, mega colon etc.
7. Induced Delivery
8. Oxytocin induction and augmentation .
9. Epidural Analgesia.
10. Antepartum Hemorrhage
11. Twin Pregnancy
12. Prolonged PROM

Indication for Augmentation-

1. Prolonged Labour
2. Cervical Dystocia
3. Arrest of Dilatation.
4. Arrest of Labour
5. Non Progress of Labour
6. Cervical Spasm
7. Failure to progress

They should alternately be allocated to three groups –

1. Group A – In comprised of 100 patients who had normal labour and who were not given any drugs.Control Group
2. Group B – In 100 cases augmentation of labour was carried out with 1/M Tramadol at 3cm.cervical dilatation and the protocol was as follows 100 mg i/m followed by 100 ml i/m after 3 hrs if 1st stage not crossed.
3. Group C- In 100 cases augmentation of labour was carried out with inj. Drotin 1/M at cervical dilatation at 3cm.and repeated at 2 hourly intervals if required.

In all women general examination, systemic examination and Obstetric examination including vaginal examination is to be performed. Informed consent for inclusion in the study is to be obtained. The study should be done in collaboration with a pediatrician.The patient is taken up for Designed study protocol only after she enters active phase of first stage of labor. From this point onwards all events in labor are documented on a partogram and labor is monitored by a skilled attendant.All medications will follow a preconceived and accepted protocol of drug medication. If the frequency of uterine contractions are not adequate, labor is augmented with Oxytocin infusion 5 units in 500ml of I/V fluid in escalating doses till at least 3 contractions in 10 minutes, lasting 35-45 seconds is achieved. Such patients should be excluded from the study to avoid Oxytocin as a confounding factor.To prevent maternal exhaustion and ketosis,Set up an IV infusion line using Ringer Lactate solution At 3-4 cm of cervical dilatation, administer Injection Tramadol 100 mg I/M at 3 hrly interval in Tramadol Group, and Drotaverine 40 mg at 2 hrly interval in Drotin Group .Injection Drotaverine can be repeated every 2 hours, if required, for a maximum of three doses. And in Control Group, no drug is given. During the Third stage practice of active management is recommended and is carried out by injecting 125 micro gm carboprost Intramuscularly. Once the placenta is separated add 10U of Oxytocin to 500ml of an IV infusion to promote uterine contractions and reduce bleeding.Partogram is to be plotted for the progress of labor, rate of cervical dilatation, duration of first stage of labor, number of contractions, Fetal heart rate, I/V fluids, Medications etc. It serves as the control baseline reference for all further evaluations of treatment regimes.Average blood loss is to be assessed with the help of Mop count. The outcome of Designed labor protocol is assessed with respect to

1. Mean rate of cervical dilatation
2. Mean duration of First stage of labour
3. Mean duration of Second stage of labor
4. Mean duration of Third stage of labor
5. Side effects & Complications
6. Neonatal Outcome
7. Mode of delivery
8. APGAR scores

All the above parameters is compared with 100 Patients with no high risk factors taken as Controls. Appropriate statistical analysis is to be done

OBSERVATIONS

The present study was done to evaluate the efficacy of Tramadol and Drotaverine in cervical dilatation. Three hundred cases were studied in Department of Obstetrics and Gynaecology at Kasturba Hospital, BHEL, Bhopal, 2006 to 2007. Cases were be equally grouped as follows :-

1. **Group A** - In comprised of 100 patients who had normal labour and who were not given any drugs.**Control** Group.
2. **Group B** - In 100 cases augmentation of labour was carried out with 1/M **Tramadol** at 3cm.cervical dilatation and the protocol was as follows 100 mg i/m followed by 100 ml i/m after 3 hrs if 1st stage not crossed.
3. **Group C** - In 100 cases augmentation of labour was carried out with inj. **Drotin** 1/M at cervical dilatation at 3cm.and repeated at 2 hourly intervals if required.

TABLE NO.1 AGE

Age in Yrs.	Control		Tramadol		Drotin	
	No.	%	No.	%	No.	%
≤ 20	25		24	24	22	22
21-25	60		63	63	61	61
26-30	15		13	13	17	17
≥31	-		-		-	
Total	**100**		**100**		**100**	

Table 1 shows age incidence of all three groups majority of patients belong to age group 21-25 in all three groups.

TABLE NO. 2 PARITY

Parity	Control		Tramadol		Drotin	
	No.	%	No.	%	No.	%
0	48	48	50	50	50	50
I	52	52	50	50	50	50
	100		100		100	

Table II shows parity wise distribution of cases in all three groups 50% were primiparous and 50% were multiparous.

OUTCOME OF LABOUR

The patients who were chosen for study were essentially those in whom there were no gynaecological or obstetrical complications. It was thereby foreseen that the course of labour would be normal. During the study few patients mainly of control group needed intervention to protect the baby and the mother, the results have been outlined in table below :-

TABLE NO. 3 OUTCOME OF LABOUR IN PRIMI

Mode of Delivery	Control		Tramadol		Drotin	
	No.	%	No.	%	No.	%
Spontaneous Vaginal Delivery	42	88	46	92	48	96
Forceps	4	8	2	4	2	4
LSCS	2	4	2	4	-	-

Incidence of spontaneous vaginal delivery in primiparous group A was 92% (46 patients), 2 patients had undergone lower segment cesarean section indication being fetal distress, one baby had tight loop of cord around neck. Two patients were delivered by out let forcep application for prolonged II stage. In primiparous Drotin group 96% (48 patients) had spontaneous vaginal delivery, 2 patients (4%) were subjected to out let forcep delivery indication being fetal distress and in other prolonged 2nd stage of labour. In control in primipara and in 88% cases (42 patients) delivered vaginally. Four patients (8%) were subjected to let forceps application indication being prolonged II stage in 1 case fetal distress in another. Two patients had undergone cesarean section, indication being fetal distress.

TABLE NO. 4 OUTCOME OF LABOUR IN MULTIPARA

Mode of Delivery	Control		Tramadol		Drotin	
	No.	%	No.	%	No.	%
Spontaneous Vaginal Delivery	50	96	50	100	46	92
Forceps	-	-	-	-	-	-
LSCS	2	4	-	-	4	8

All patients in multiparous Tramadol group had spontaneous vaginal delivery. In multiparous Drotin group 46 patients delivered vaginally where as 4 patients had undergone LSCS for fetal distress. In multiparous control group two patients had undergone LSCS for fetal distress.

DOSAGE SCHEDULE

TRAMADOL GROUP

This group received 100 mg Tramadol by intramuscular route at 3 hourly interval. The dose was repeated if required.

TABLE NO. 5 DOSAGE SCHEDULE IN PRIMI TRAMADOL GROUP

Drug (mg) Tramadol	Parity PRIMI	Nos.	%	No. of injection required
100 mg	-	16	32	1
200 mg	-	32	64	2
300 mg	-	2	4	3

Table (5) shows the relation of no. of injections received by primi para. It is evident that 16 (32%) patients delivered after single dose, 32 (64%) patients delivered after 2 injections and patients requited 3rd injection given at interval of 3 hours.

TABLE NO. 6 DOSAGE SCHEDULE IN MULTI TRAMADOL GROUP

Drug (mg) Tramadol	Parity Multi	Nos.	%	No. of injection required
100 mg	1	36	72	1
200 mg	1	12	24	2
300 mg	1	2	4	3

Maximum no. of patients (72%) delivered after single injection of Tramadol. 12 patients (24%) delivered after 2 injections and only 2 patients (4%) required 3 injections.

DROTIN GROUP

Patients in this group received 40 mg Drotaverine intramuscularly at 2 hourly interval.

TABLE NO. 7 DOSAGE SCHEDULE IN PRIMI DROTIN GROUP

Drug (mg) Tramadol	Parity PRIMI	Nos.	%	No. of injection required
40 mg	-	8	16	1
80 mg	-	8	16	2
120 mg	-	28	56	3
160 mg	-	6	12	4

Maximum no. of primi patients (56%) required 3 injections (120), 16% of patients required 1 injection (40 mg), 16 % (8 patients) required 2 injections (80 mg) 6 patients required 4 injections of Tramadol (160 mg).

TABLE NO. 8 DOSAGE SCHEDULE IN MULTI PAROUS PATIENTS (DROTIN GROUP)

Drug (mg) Tramadol	Parity Multi	Nos.	%	No. of injection required
40 mg	1	11	22	1
80 mg	1	29	58	2
120 mg	1	6	12	3
160 mg	1	4	8	4

Twenty two percent in the above group required 1 injection of Drotin, 29 (58%) of patients delivered after 2 injection i.e. 80 mg of Drotin. Six patients (12%) required 3 injections (120 mg) and only 4 patients (8%) delivered after 4 injections of Drotin (160 mg).

TABLE NO. 9 MEAN DURATION OF ACTIVE PHASE OF LABOUR

Parity	Control	Tramadol	Drotin
Primi S.D.	5 hrs 48 mins ± 1 hr 23 mins	4 hrs mins ± 1 hr 28 mins	4 hrs ± 1 hr 36 mins
Multi S.D.	4 hrs 43 mins ± 1 hr 7 mins	3 hrs 19 mins ± 1 hr 5 mins	3 hrs 25 mins ± 1 hr 4 mins

Mean duration of active phase of labour in primi control group was 5 hrs 48 mins ± 1 hr 23 mins whereas in Drotin and Tramadol group it was 4 hrs ± 1 hrs 28 min and 4 hrs 10 mins ± 1 hrs 36 mins respectively. Table showing duration of active phase by 1 hr 41 min in Tramadol and 1 hr 48 mins in Drotin. In multi control group mean duration of active phase of labour was 4 hrs 43 mins ± 1 hr 7 min whereas in Tramadol and Drotin group it was 3 hrs 19 min ± 1 hr mins and reduction in Tramadol group by 1 hr 24 mins and in Drotin group 1 hr 18 mins.

INJECTION- DELIVERY INTERVAL

The effect of drugs is on the active phase of labour or stage of cervical dilatation. Injection delivery interval was taken as duration of delivery after administration of injection Tramadol or Drotin or when a patient had entered the active phase in control group.

TABLE NO. 10 INJECTION-DELIVERY INTERVAL

Parity	Control	Tramadol	Drotin
Primi S.D.	4 hrs 21 mins ± 1 hr 33 mins	4 hrs 25 mins ± 1 hr 33 mins	6 hrs 14 mins ± 1 hr 30 mins
Multi S.D.	3 hrs 32 mins ± 1 hr 42 mins	3 hrs 30 mins ± 1 hr 20 mins	4 hrs 58 mins ± 1 hr 5 mins

Injection delivery interval as shown in above table I-D interval in primi Tramadol is 4 hrs 25 mins ± 1 hr 33 mins. Whereas in control group it was 6 hrs 14 mins ± 1 hrs 30 mins. In multi Tramadol group it was 3 hrs 32 mins ± 1 hr 42 mins. In multi Drotin group it was 4 hrs 25 mins ± 1 hr 33 mins & in multi control group it was 4 hrs 58 mins ± 1 hr 5 mins.

TABLE NO. 11 DURATION OF II STAGE OF LABOUR

Parity	Control	Tramadol	Drotin
Primi S.D.	23 mins 5 sec ± 8 mins 6 sec	21 mins 17 sec ± 2 mins 25 sec	22 mins 25 sec ± 6 mins 1 sec
Multi S.D.	15 mins 45 sec ± 5 mins 15 sec	14 mins 2 sec ± 5 mins 36 sec	13 mins 54 sec ± 5 mins 18 sec

The above table shows the duration of II stage of labour in all three groups. The drug did not affects the second stage of labour.

TABLE NO. 12 DURATION OF III STAGE OF LABOUR

Parity	Control	Tramadol	Drotin
Primi S.D.	10 mins 42 sec ± 3 mins 14 sec	10 mins 17 sec ± 2 mins 25 sec	10 mins 25 sec ± 4 mins 31 sec
Multi S.D.	9 mins 25 sec ± 3 mins 13 sec	10 mins ± 4 mins 6 sec	9 mins 15 sec ± 3 mins 6 sec

The above table shows the duration of III stage of labour in all three groups. Both drug did not affects the third stage of labour.

TABLE NO. 13 (cm/hr) RATE OF CERVICAL DILATATION

Parity	Control	Tramadol	Drotin
Primi	1.2 cm/hr	1.71 cm/hr	1.70 cm/hr
Multi	1.48 cm/hr	2.1 cm/hr	2.0 cm/hr

The rate of cervical dilatation in primi control group was 1.2 cm/hr whereas in Tramadol & Drotin it was 1.71 cm/hr and 1.70 cm/hr respectively which is approximately 0.50 cm/hr more than control group. In multigravida rate of cervical dilatation in control group was 1.48 cm/hr whereas with Tramadol and Drotin it was 2.1 cm/hr and 2.0 cm/hr respectively.

TABLE NO. 14 APGAR SCORES

Score	Control	Tramadol	Drotin
1 mins	9.12	9.5	9.2
5 mins	9.84	9.98	9.89

Above table show apgar scores at 1 min & 5 min in all three groups Apgar score at 1 min was 9.12, 9.5, 9.2 in control, Tramadol and Drotin group respectively. Apgar score at 5 min was 9.84, 9.98, 9.84 in control Tramadol, Drotin respectively. Only one of Tramadol group had moderate asphyxia at 1 min (score 7) recovered after resuscitation (score 9) at 5 min. One baby of Drotin group had severe asphyxia .At birth, Apgar score at 1 min was 4 and at 5 min it was 7. Baby was resuscitated and discharged on 5th day from nursery. Two babies in control group had severe birth asphyxia at birth. One of them improved after resuscitation and was discharged on 5th day while other baby had severe birth asphyxia even after 5 min and died on 2nd day. Rest of babies had Apgar score of > 7 at min and 5 min after birth.

TABLE NO. 15 NEONATAL OUTCOME

Complications	Control	Tramadol	Drotin
Birth Asphyxia	2	1	1
Neonatal Jaundice	2	2	1

Table 15 shows neonatal complications in all three groups complications are more or less equal in all three groups.

TABLE NO. 16 SIDE EFFECTS

Side Effects	Tramadol	Drotin
Nausea	6%	8%
Vomiting	3%	4%
Drowsiness	2%	-
Headache	2%	-
Tachycardia	-	2%
Flushing of face	-	2%

Only six patients had nausea and three patients had vomiting in Tramadol group two patient and drowsiness two had headache in Tramadol group whereas in Drotin group eight had nausea, four had vomiting, two had tachycardia, two had flushing of face.

TABLE NO. 17 COMPLICATIONS

Complications	Control		Tramadol		Drotin	
	No.	%	No.	%	No.	%
Prolonged 2nd stage	-	-	2	2	1	1
PPH	4	4	4	4	4	4
Vaginal Tear	2	2	4	4	2	2
Cervical	4	4	-	-	4	4

Table 17 shows maternal complications in all the 3 groups Incidence of postpartum hemorrhage was same in all three groups. PPH was mild in nature and none of the patients requited blood transfusion. Two patients of Tramadol group and one patients of Drotin group had prolonged 2nd stage of labour for which outlet forceps were applied. Two patients of control and Drotin group each and 4 patients of Tramadol group had vaginal tear. Four patients each of Drotaverine and control group had cervical tear.

DISCUSSION

One of the most important stage of labour is the so called dilatational stage which last from the beginning of labour to the effaced fully dilated cervical os. Distraction dynamics are of great, importance to the mother and the fetus. Prolonged dilatational stage (8 hrs.) may lead to exhaustion and increased psychological burden on the mother and these events may be then the underlying cause of problem in the puerperium. Attempts to reduce the duration of this phase have continuously been made by obstetricians. Present study was carried out to evaluate the effect of Drotaverine hydrochloride and Tramadol hydrochloride on cervical dilatation and to compare it with control group. Analysis of three hundred cases is presented, out of which in hundred cases, augmentation of labour done with Tramadol and in another hundred cases with Drotin. The control group comprised of one hundred cases where no augmentation was done. All the cases were identical with respect to parity and gestational age (37-41 weeks).

AGE

In the present study, majority of patients belong to age group of 21-25 yrs in all the three groups.

PARITY

As far as parity was concerned, equal number of cases were taken in each group. They comprised of equal number of primi and Multi para with 50 patients in each group.

OUTCOME OF LABOUR

As both the drugs Tramadol and Drotin reduce the duration of 1st stage, less operative interference was required in these two groups in comparison to control group. In the present study 92% of primi Tramadol group (46 patients) had spontaneous vaginal delivery. 4% of patients i.e. 2 patients had forceps delivery for prolonged second stage of labour. Two patients had undergone lower segment cesarean section for fetal distress. One baby had tight loop of cord around the neck. All multipara in Tramadol group had spontaneous vaginal delivery. In primi Drotin group 96% i.e. 48 patients had spontaneous vaginal delivery. Two patients delivered by outlet forceps application, one for fetal distress and other for prolonged second stage of labour. In Drotin group 92% in multipara i.e. 46 patients delivered vaginally and 8% i.e. 4 patients delivered by lower segment cesarean section for fetal distress. In prirni control group only 88% i.e. 42 patients delivered by spontaneous vaginal delivery. 8% i.e. 4 patients required outlet forceps (3 for fetal distress and One for prolonged second stage of labour). Two patients had undergone lower segment cesarean section (one for fetal distress and one for non progress of labour). In multipara control group 96% i.e. 50 patients had spontaneous vaginal delivery. Two patients 4% had undergone lower segment cesarean section for fetal distress. Hence it could be observed that incidence of operative interference was significantly decreased in Tramadol and Drotin group compared to control group. In the study conducted by B. Sarkar, A.K. Mukhopadhyay (1995)[12] 100 mg ihn Tramadol was given. Duration of labour was shortened and incidence of cesarean section decreased and incidence of fetal distress was significantly reduced. Mild fetal distress was observed in 70% of Tramadol cases. Forceps was applied in 13.4% of Tramadol group as compared to 22% of control group and cesarean section was performed in 17.9% in Tramadol group as compared to 23% in control group.

DOSAGE SCHEDULE

In Tramadol group 32% patients received 100mg of Tramadol where as 200 tug was required in 64% of the patients and only 4% had 300 mg. In majority of multipara patients 72% only 100 mg. of Tramadol was required whereas only 24% required 200 mg and 4% required 300 mg. As no. of injections required were less, the cost effectiveness of drug was increased. In Drotin primi group majority of patients (56%) required 120 mg i.e. 3 ampoules of Drotin, I'5% delivered by 40 mg, 16% by 80 mg and and 80 mg and 12% by 160 mg. As the drug is given at more frequent interval the cost effectiveness of the drug is less. Two injections were required in 58% of multipara whereas 22% required one injection only. Only 12% and 8% of the cases in this group required 3 and 4 injection respectively.

OXYTOCIN AUGMENTATION

In present study majority of patients in each group had normal uterine contractions . **Cases who were, who had hypotonic uterine contractions and were given oxytocin by i.v drip for augmentation of labour ; such patients were not included in the study to avoid Oxytocin as an confounding factor for shorter duration of labour** B. Sarkar, A.K. Murhkopadhyay[12] in their study observed (1995) 100mg i/m Tramadol in cases of dysfunctional labour in North Bengal medical college. They noted remarkable normality of irregular uterine contractions. Tramadol had good effect in each of

violent and excessively painful contractions. No effect was noticed by Schmidt (1957)[13] and Meir (1958)[14] on tone of uterus by Drotin. These workers assessed the uterine tone clinically. Kishore (1979)[15] studied the tone of uterus by tonometric method and corroborated the same.

EFFECT ON ACTIVE PHASE OF LABOUR

The Criteria to use the drugs Tramadol and Drotin were as follows when patient was in active labour i.e. there was at least 3 cm cervical dilatation with partially effaced cervix. Satisfactory 3 contractions per 10 min of 45 sec. duration. Thus the drug was used in patients who were in active phase of labour. In primi control group the active phase of labour was 5 hrs 50 mins approx. In primi Tramadol group it was 4 hrs. 7 mins. and in primi Drotin group it was 4 Firs. Thus both Tramadol and Drotin reduced the active phase of labour by 1 hr 40 mins approximately. Reduction of active phase of multi Tramadol group was by 1 hr 24 mins and in multi Drotin group it was by 1 hr 18 mins. Tramadol causes sympathetic blockage. Pain of parturition if not adequately controlled can lead to wide spread maternal sympathetic activation which causes increase in B.P., Pulse rate, cardiac output. Increased catecholamine release of mother due to pain cause 35-70% decrease in uterine blood flow and longer labors. Women usually hyperventilate in response to pain which shifts the maternal oxygen hemoglobin dissociation curve to the left thus interfering with fetal oxygenation. Tramadol reduces the duration of active phase without altering the mechanism of labour. Suvormakote et al (1986), observed that there were rapid progression in labour in patients receiving Tramadol. Since uterine contractions were not monitored by to codynamometry nor intrauterine pressure measured, it was difficult to explain such events. In a study conducted by Turi Blasko S.J. Demeter (1998) the average time duration of dilatational phase (in minutes) in group A (Drotaverine) was 183.6±121.1, in group B (Control group) was 236.2±138.6. There was significant difference between the two groups regarding the length of dilatational phase.

CERVICAL DILATATION

In present series the average average rate of cervical dilatation was 1.71 cm/hr in primi Tramadol group and 2.1 cm/hr in multi Tramadol group. Tramadol increased the rate of cervical dilatation by 0.51 cm/hr in primipara while in multipara it was increased by 0.62 cm/hr. In Drotin group mean rate of cervical dilatation was 1.70 cm/hr in primipara and thus it increased the rate of cervical dilatation by 0.50 cm/hr. Rate of cervical dilatation in multipara increased by 0.52 cm/hr. Thus there was significant increase in rate of cervical dilatation in Tramadol and Drotin group compared to control group.

INJECTION – DELIVERY INTERVAL

The injection delivery internal closely followed the same trends as mean labour data. This confirmed the view that Tramadol and Drotin were the main determinants in reduction of duration of labour. The I-D interval in primi Tramadol group was 4 hrs 21 mins and in multi Tramadol group was 3 hrs 32 mills. In primi Drotin group injection-delivery interval was 4 hrs 25 mills where as in multi Drotin group it was 3 hrs 30 mins. The observation delivery interval when patient entered the active phase of labour till she delivered) in primi control group was 6 hrs 14 mins and in multi control group it was 4 hrs 58 mins. Thus there was reduction by 1 hr 56 mins in primi Tramadol group, 1 hr 20 min in multi Tramadol group. The reduction in primi Drotin group was 111r 49 min and 1 hr 28 mins in multi Drotin group. In a study conducted by Prasereawat et al (1986), out of 45 patients who were given 100 mg Tramadol, 5 patients delivered between 30-60 minutes, 6 patients delivered between 1.01-1.30 hr, 8 patients delivered between 1.30-2.00 h, 4 patients delivered between 2.01-2.30 hr, 3 patients delivered between 2.30-3.0010 patients delivered between 3.01-4.00 hr and 9 patients at greater than 4 hrs. B. Saikax et al. (1995) did not specify the period. In 92% of cases the drug delivery interval was between due to eight hrs.

SECOND STAGE OF LABOUR

In present study mean duration of second stage of labour in Tramadol group was 21 mins 17 sec (± 2 min 25 sec) in primi patients, and 14 mins 2 sec (±5 min .35 sec) in multi patients. In Drotin group mean duration of second stage of labour in primi patients was 22 mins 25 sec (±8 min 6 sec) and in multi patients it was 15 min 45 sec (± min 15 sec). Overall there was no significant reduction in the second stage of labour in Tramadol and Drotin group. This shows that Tramadol and Drotin mainly affected the dilatational phase of labour. No significant shortening of duration was noticed in second and third stage of labour in previous studies of Beck (1956), Walter (1957) and Schmidt (1957). In study conducted by Turi Blasko (1998) the average duration of second stage in minutes) in Drotin group was 15.2±11.8 and in control group it was 13.7±8.5.

THIRD STAGE OF LABOUR

In present study mean duration of third stage of labour in primi Tramadol group was 10 min 17 mins (±2 mins 25 sec), in multi Tramadol group, it was 10 mins (± 4 mins 6 sec). Duration of third stage of labour in primi Drotin group was 10 min 25 sec (±4 min 3 sec) in multi it was 9 min 15 sec (±3 min 6 sec). The observation made in the present study suggested that Tramadol and Drotin had no remarkable effect on duration of third stage of labour. It did not reduce the uterine tone in the period following delivery. Turi Blasko (1998) observed that average duration of the placental stage (in minutes) in Drotin group was 10.1±40 and in control group it was 11.0±6.3. There was no significant difference in perinatal blood loss in both groups.

APGAR SCORE

To determine the effect of acceleration of labour on the neonatal outcome APGAR scoring was carried out, on all babies at 1 mm & 5 min after birth. - There was no significant difference in the APGAR score of babies delivered with the aid of Tramadol and Drotin as compared to control group. Mean Apgar score in Tramadol group babies at 1 mm was 9.5 and 5 min it was 9.98. Bitsch et al 1980 observes that apgar score at 1 minute /10 minutes was 8.2/9- 10 for Tramadol. None of the 23 patients had bradycardia. In their study

Suvannakote et al (1986) observed that 8 infants in Tramadol group had respiratory depression. Of these 4 had respiratory depression, necessitating end tracheal intubations and i/m injection of antidote naloxone HCL. The other 4 only required observation in the incubator. The respiratory effect of Tramadol on neonates, as judged by apgar score was not significant as all babies had apgar score greater than 7 at 1,2,5, 10 mins. (Praserswat et al 1986). Apgar score observed with Tramadol administration at 1 minute was 9-10 in 6%, 7-8 in 34%, a 4-6 in 5% neonate. The apgar score of 7-10 at 1 minute (92.9% Vs 66%) was far better in control group, which consisted of patients who were given pethidine. Bajaj et al 1997 observed that apgar score was above 8 in all neonates. Only 4.4% of neonates had moderately reduced Apgar score, the cause being face presentation and with a loop of cord around the neck. In the study by S.N. Daftary et al (1991) on Drotin, there were two babies who were born with Apgar score of less than 7 who required resuscitation but both the babies survived.

NEONATAL COMPLICATIONS

Tramadol has been shown to cross placenta but no adverse effect has been noted on neonatal outcome. Neonatal complications were more or less same in all three groups except for 1 death in control group. Birth asphyxia occurred in 2 cases in control group and 1 case in Tramadol and 1 case in Drotin group. One baby died of birth asphyxia (control group) on 2nd day. Neonatal jaundice was found in two cases in control, two cases in Tramadol group and one case in Drotin group. All had mild jaundice, which improved by conservative management only.

SIDE EFFECTS

In the present study nausea in Tramadol and Drotin group was 65% & 8% respectively. With Tramadol 3% patients had vomiting 2% had drowsiness, 2% patients complained of headache. All the sides effects were mild. No patients had respiratory depression. With Drotin-4% of patients had vomiting, and 2% had flushing of face. Bhan et al also reported significant tachycardia in their study. Hypotension as an effect of Drotaverine administration was not observed by Turi Blasko (1998)

CONCLUSION

Both Tramadol and Drotaverine reduce the duration of first stage, less operative interference was required into two study groups in comparison to control group, in both primpara and multi para patients. Results of both drug are comparative.Among primiparous patients, two each of Tramadol and Drotaverine group had forcep delivery and two patients of Tramadol group had undergone lower segment cesarean section.Among multiparous patients, four patients of Drotaverine group delivered by lower segment cesarean section. Both the drugs had no significant action on the uterine contraction . Both the drug reduce the duration of active phase of labour and there who significant increase of rate of cervical dilatation in Tramadol and Drotaverine group compared to control group.Both the drugs had no significant effect on duration of second and third stage of labour. There was no significant difference in the APGAR score of babies delivered with the aid of Tramadol and Drotaverine as compared to control group.Both the drugs had minimal side effects and complications. It can be opined that Tramadol hydrochloride is a good cervical dilator and its effects is comparable to Drotaverine hydrochloride but due to its added analgesic effects, Tramadol can be preferred over Drotaverine hydrochloride and other cervical dilators for augmentation of labour. But further studies are required to have the data sufficient enough to establish the drug as better cervical dilator than Drotaverine.

BIBLOGRAPHY

[1]. Dencker 2009 -Dencker A, Berg M, Bergvist L, Ladfors L, Thorsen LS, Lilja H. Early versus delayed oxytocin augmentation in nulliparous women with prolonged labour - a randomised controlled trial. BJOG: an international journal of obstetrics and gynaecology 2009;116:530-6.

[2]. Neilson 2003 -Neilson JP, Lavender T, Quenby S, Wray S. Obstructed labour. British Medical Bulletin 2003;67:191-204.

[3]. WHO 1994 -World Health Organization maternal health and safe motherhood programme. World Health Organization partograph in management of labour. Lancet 4 June 1994;343(8910):1399-404.

[4]. Lavender 2009 -Lavender T, Hart A, Smyth RMD. Effect of partogram use on outcomes for women in spontaneous labour at term. Cochrane Database of Systematic Reviews 2009, Issue 3. [DOI: 10.1002/14651858.CD005461.pub2]

[5]. Neal 2010 -Neal JL, Lowe NK, Patrick TE, Cabbage LA, Corwin EJ. What is the slowest-yet-normal cervical dilatation rate among nulliparous women with spontaneous labor onset?. Journal of Obstetric, Gynecologic, and Neonatal Nursing : JOGNN 2010;39:361-9.

[6]. O'Driscoll 1973 -O'Driscoll K, Stronge JM, Minogue M. Active management of labour. British Medical Journal 1973;3:135-7.

[7]. O'Driscoll 1994 -O'Driscoll K. Active management of labour. True purpose has been misunderstood. BMJ 1994;309(6960):1015.

[8]. Brown 2008 -Brown HC, Paranjothy S, Dowswell T, Thomas J. Package of care for active management in labour for reducing caesarean section rates in low-risk women. Cochrane Database of Systematic Reviews 2008, Issue 4. [DOI: 10.1002/14651858.CD004907.pub2]

[9]. Wei 2009 -Wei S, Wo BL, Xu H, Luo ZC, Roy C, Fraser WD. Early amniotomy and early oxytocin for prevention of, or therapy for, delay in first stage spontaneous labour compared with routine care. Cochrane Database of Systematic Reviews 2009, Issue 2. [DOI:10.1002/14651858.CD006794.pub2]

[10]. Principles and Practice Of Obstetrics & Gynaecology for Postgraduates'.2nd Edition, 2003, FOGSI publication, Shirish N Daftary - Modern Management of Labor.

[11]. Veronica Irene Yuel, Vaneet Kaur, Dilpreet Kaur,'Programmed Labor For Optimizing Labor And Delivery' J K Science, Volume 10 No:3 April-June 2008

[12]. B. Sarkar, A.K. Mukhopadhyay Tramadol HCL in dysfunctional labour a clinical trial. The journal of obstetrics and gynecology of India vol-47 No.1 Feb.1997.

[13]. Schmidt 1988 Schmid G, Stolla R. Intrauterine Druckmessung beim Rind mittels Mikrotransducern. Tierärztl Umsch 1988;43:439-444.

[14]. Meier G.G ;Rrztt Prazis 1958,32;738

[15]. Kishore N. Shrivastava M. Sarkar D. kishore N. Effect of Epidosin in normal labour the journal of obst & gynae of India April 1979 Vol XXIX pp 384 – 388

[16]. Daftary 5N. Journal of Obstetrics and Gynaecology of India, 1977;27:687

[17]. Daftary SN, Desai SV, Nanavati MS et al. Programmed labour – An indigenously developed protocol of labour management. Int J Gynaecol Obstet. 2003; 6:47-9.

[18]. Bajaj P Meena R, Prasad R, Tramadol in labour. The Indian practice 1997: 50(12): 1051-1054.