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Research Paper

To Evaluate The Efficacy of Drotavarine & Tramadol in all Primigravida in Providing Safer Shorter & Relatively Free Delivery

Medical Science

KEYWORDS : Labour analgesi Drotavarin Tramadol Pain free

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ABSTRACT

Background: Normal labour composes of integration of the Three 'P's namely, 1.The "Powers" or driving forces provided by the uterine contractions,2.The "Passenger" or the fetus of optimum size and in favourable presentation and position.3. "Passages" or the birth canal composed of the soft tissues and the bony pelvis being adequate in capacity. Pain in labor is unpleasant and distressing to the patient. Pain relief during labour is very important as it allays fear and anxiety and provides a more favourable environment for improved obstetric outcome. This also helps in cervical dilation resulting in labours of shorter duration, less traumatic and requires lesser obstetric interventions. It helps prevent the undue muscular efforts of the mother which exhaust her . The objective of the current study is to evaluate the efficacy of drotavarine and tramadol in primigavidae to provide safer ,shorter and relatively pain free labour Methods In this study 200 primigravida patients admitted in labour at tertiary care hospital in Mumbai during period of 1 year from Dec 2011-Nov2012 were recruited .Primigravida with GA of 37-41 weeks with no obstetrical or medical complications.,.singleton pregnancy with cephalic presentation. & adequate pelvis were selected . Multigravide , Patients with abnormal presentation & cephalo-pelvic disproportion were excluded These 200 patients were equally divided in 2 groups by randomisation 1. Receiving injectable drotaverine and tramadol. 2. Not receiving any of two drugs. After entering active phase of labour i.e. 3cms of cervical diltation, partogram was plotted in all patients To optimise pain relief and facilitate cervical dilatation intramuscular tramadol in dose of 100mg along with intravenous drotaverine 40mgs 1hourly for three doses administered only in the study group. In the study group intravenous drotaverine was repeated 1hourly for maximum three doses and as duration of action of tramadol is 4-6 hours so single dose was sufficient.

Results - Pain relief score of patients included in the study group was noted on rupees scale. RUPEES SCALE . Grade 1- No pain . Grade 2-Mild pain but comfortable-25% . Grade 3-Moderate pain with discomfort-50% Grade 4-Maximum pain/ Severe pain -75%or more Pain relief score, Duration of 1stand 2nd stage of labour. Mode of delivery. Neonatal Apgar at 1 and 5 mins. were the outcomes measured

Conclusion There was statistically significant reduction in duration of 1st stage of labour in the study group as compared to the control group. However , there was no statistically significant difference in duration of 2nd stage of labour in both the groups. Overall 84% patients in the study group delivered within 6 hours whereas only 59% of the control group delivered within 6 hours.Majority of the patients in the study group had vaginal delivery as compared to the control group. After administration of tramadol none of the patients in the study group experienced severe pain ,majority of them had moderate pain relief. In the control group maximum patients experienced severe pain. With regard to neonatal outcome none of the baby from the study group had respiratory depression or required NICU admission. Only minor side effects were observed in 19% of cases.

INTRODUCTION

The experience of childbirth is as varied as a woman's mind! It has been described in various terms ranging from worst possible agony to total ecstasy. In a scholarly review, Lowe(2002) emphasized that the experience of labour pain is highly individual reflection of variable stimuli that are uniquely received and interpreted by each women. These stimuli are modified by emotional, motivational, cognitive, social, and cultural circumstances.1 Epidural analgesia has proved to be beneficial and has contributed significantly to pain relief, however in India,wherein majority of women are delivered at small community hospital facilities for providing epidural analgesia is not practical for all class of patients. After a long research a protocol was developed to optimize labour outcome i.e. pain relief, short labour, less blood loss, This optimised labour protocol refers to ensuring smooth progress of labour resulting in delivery of healthy baby by vaginal route through judicious use of labour inducer ,appropriate analgesia regime with partographic monitoring.2 Therefore the present study is designed to evaluate the efficacy of drotaverine and tramadol in providing shorter, safer and relatively pain free delivery. Active management of labour was a concept advanced by Irish school which reported on the advantages of active management of labour resulting in shorter labours, improved obstetric outcome and lower caesarean section rates3 . This study incorporates these principles advantageously.

Aims & Objectives

1, To study the efficacy of drotaverine in accelerating mean rate of cervical dilatation
2. To study the efficacy of tramadol for pain relief.
3. Duration of first stage (active phase) of labour
4. Maternal and neonatal outcome.

Material & Methods

The present study was conducted in 200 primigravida , at a tertiary care hospital, in active labour. It was a randomised control trial to study the efficacy of intramuscular tramadol for pain relief and intravenous drotaverine for augmentation of labour and also mode of delivery, maternal and neonatal outcome. In this study, two groups were made, cases and controls, matched for age. Case group received injectable drotaverine and tramadol after entering active phase of labour. Control group didn't receive any of these two drugs. Primigravida with GA of 37-41 weeks with no obstetrical or medical complications ,singleton pregnancy with cephalic presentation. & adequate pelvis were included in the study. Infrastructure for obstetric intervention & facilities for medical supervision and clinical monitoring were kept ready . Fetal heart monitoring & partograph was plotted These 200 patients were equally divided in 2 groups by randomisation

1. Receiving injectable drotaverine and tramadol.
2. Not receiving any of two drugs

After entering active phase of labour i.e. 3cms of cervical dilatation the following regime was followed:- - amniotomy was done and the colour of liquor noted, only patients with clear liquor 4 were included in the study. Baseline fetal heart rate tracing were

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done, -Labour pains were optimised with oxytocin 5U in 500 ml ringer lactate by titration method to ensure adequate uterine contractions . -To optimise pain relief and facilitate cervical dilatation intramuscular tramadol in dose of 100mg along with intravenous drotaverine 40mgs 1hourly for three doses were administered only in the study group. -A partogram plotted for all 200 patients and all labour events charted on the partogram to guide in patient management. -In the study group intravenous drotaverine was repeated 1hourly for maximum three doses and as duration of action of tramadol is 4-6 hours so single dose was required. Duration of first and second stage stage of labour, mode of delivery, neonatal APGAR scores at 1min and 5 mins at birth were noted. After delivery the duration of first and second stage of labour, pain relief score of patients included in the study group ws noted on rupees scale.

RUPEES SCALE Grade 1- No pain
Grade 2- Mild pain but comfortable-25%
Grade 3-Moderate pain with discomfort-50%
Grade 4-Maximum pain/ Severe pain -75%or more

Often the causes are inadequate pains either in intensity or are infrequent in which case labour is accelerated with oxytocin. If the pains be incordinate, analgesics help to relieve pain and correct the incordinate uterine activity, thereby reducing the incidence of cervical dystocia.9. Alert line and action 11 line are drawn to draw obstetrician attention to impaired progress of labour, so as to adopt corrective measures in time and to detect underlying factors like fetal malpositions ie occipito posterior position

Results & Obervations
Duration of labour: In the present study with 100 cases, mean duration of active phase of 1ststage of labour is 259.10 minutes with a standard deviation of 67.3 minutes. While in the control group the mean duration of labour is 335.10 minutes with a standard deviation of 37.28 minutes

Table 1 Duration of Labour

Group	Mean duration	SD of duration	Pvalue
Caes	259.10	67.3	0.0001
Controls	335.10	37.28	

It is very clear that there is stastically significant reduction in the duration of 1 st stage of labour in the cases group.

Figure 1 This is a graphical presentation of duration of 1st stage of labour in the cases and control groups

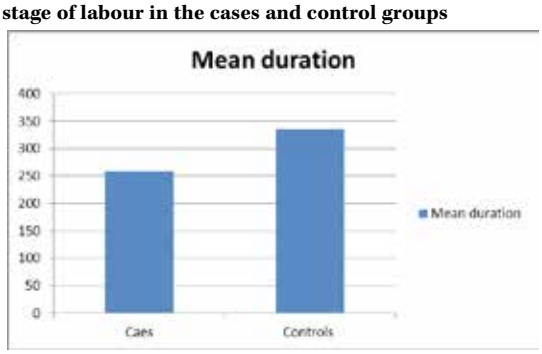
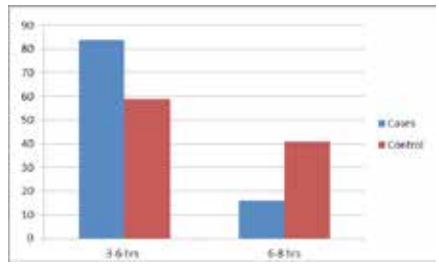


Table- 2 Total duration of labour:

	3-6 hrs	6-8 hrs	Total cases
Cases	84	16	100
Control	59	41	100

FIGURE 2 graphical presentation of total duration of labour



This is a graphical presentation of total duration of labour in both the cases and control groups, clearly showing reduction in duration in labour in the study group.

Pitocin augmentation: Out of 100 cases studied, 65% required Pitocin augmentation of labour to optimize uterine activity, while in the control group 78% required pitocin augmentation of labour. This difference was found to be statistically significant. It clearly shows that in the case group there was statistically significant reduction in the requirement of Pitocin augmentation.

Mode Of Delivery: The mode of delivery whether vaginal, instrumental or caesarean section studied in both the cases and control groups. Out of 100 cases studied, 97 subjects had normal vaginal delivery and remaining 3 underwent caesarean section. In the control group, 89 subjects had normal vaginal delivery, 6 had caesarean section and remaining 5 required assisted forceps delivery.

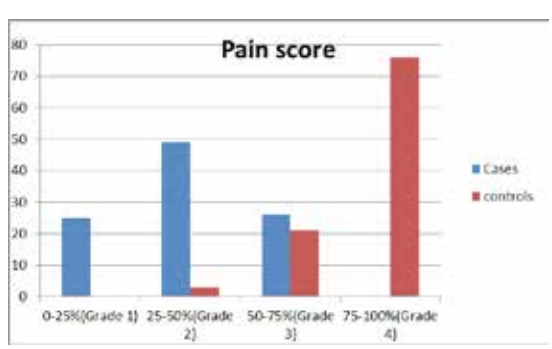
Table-3 Mode of Delivery

Mode of Delivery	Cases	Controls
Vaginal	97	89
C.Section	3	6
Forceps	0	5
Total	100	100

It is evident that statistically significant number of subjects have normal vaginal delivery in the cases group as compared to the control group

Pain relief score:
After administration of drug in 100 cases in active phase of labour , maximum patients in case group i.e.,49% had only Grade 2 degree of pain, 26% had Grade 3, 25% had Grade 1 whereas none of them had Grade 4 pain. While in the control group who do not receive any pain relief, maximum subjects i.e., 76% had Grade 4 pain, 21% had Grade 3 pain, only 3% had Grade 2 pain whereas none of them experienced Grade 1 pain.

Figure 3



Neonatal Outcome: Out of 200 babies born, 194 had an Apgar at 1min as 9 and only 6 had Apgar score less than 9 at 1 min. Of these 6 had a score of 7. Severe birth asphyxia with very low Apgar scores less than 3 was not seen in the study in any of the 2

groups. Out of the 6babies with Apgar score of 7 , 3 were in the case group whereas 3 were in the control group. No difference was noted in the two groups

Side effects of drugs: Out of 100 cases receiving two drugs, 71% experienced no side effects with drotaverine and tramadol. The most common side effect seen with the use of these drugs was nausea seen with 17 cases, the second most common side effect was vomiting seen in 10 cases. Other common side effects includes drowsiness seen in 1 patient and headache seen in 1

DISCUSSION

Drotaverine is a derivative of papaverine and has marked smooth muscle relaxant properties and minimal anticholinergic property. It is a selective inhibitor of phosphodiesterase 4 blocking one of the 5 subtypes of the enzyme phosphodiesterase and thereby prevents inactivation of intracellular second messenger cyclic adenosine monophosphate (cAMP) and cyclic guanosine monophosphate (cGMP)by respective PDE subtypes.6 It is safe in pregnancy and has no embryotoxic effects. Its action is seen only in lower uterine segment during labor as the muscle fibers in upper uterine segment are strongly affected by contractile effect of oxytocin

Systemic opioid like meperidine (Pethidine) has been used as labor analgesic for many years,but due to side effects like neonatal respiratory depression its use is limited. With the aim to reduce side effects and improve analgesia, many alternatives to meperidine have been under investigation.Tramadol is a weak opioid analgesic with the same analgesic efficacy like meperidine, less maternal sedative effect and less neonatal respiratory depression. It has does not adversely affect uterine contractility and has least potential among the opiods to cause respiratory depression in the newborn.5 The need of painless labour is no longer a controversy.

The mean duration of active phase of labour in the study group receiving drotaverine and tramadol was 259.10 minutes with a SD of 67.3 minutes, rate of cervical dilatation 1.62cm/hour . Whereas in the control group , the duration of active phase of labour was 335.10 minutes with a SD of 37.28 minutes, rate of cervical dilatation 1.25 cm/hour . This difference was found to be statistically significant . 5,6 The mean duration of second stage of labour in the study group was 35.10 minutes with a SD of 9.53 minutes .Whereas in the control group , the duration was 37.28 minutes with a SD of 13.04 minutes . This difference was not statistically significant . 84% patients in the study group delivered within 6 hours whereas in the control group only 54% patients delivered within 6 hours.

Table 4 comparison between the present study and similar studies

	Sharma J B (2001)	G Bindiya et al(2007)	Madhu C (2010)	Present study
Mean duration of labour(mins)	193.96	288	183.2	259.10
Mean rate of cervical dilatation cm/hr	1.62	2.6	3	1.62
% of patients delivered within 6hrs	84%			84
Total	50	50	49	100

In the present study out of 100 patients receiving tramadol 25% had mild pain relief, 75% had moderate pain relief and none of them experienced severe pain . This assessment holds well with the studies conducted earlier

Table 5 Studies compairing pain relief

Degree of pain relief	Thakur Ratna (2003)	Prasertsawat 1986	Bajaj 1997	Prabha singhal (2006	Nagaria Tripti	Sudha Patil 2012	Present study
No relief	14	22	20	0	9	0	0
Mild Relief	16	0	33	14	16	12	25
Moderate Relief	55	53	38	32	38	30	49
Complete Relief 15	15	25	9	54	37	58	26

This proves that tramadol acts as a good labour analgesic

Conclusions

There was statistically significant reduction in duration of 1st stage of labour in the study group as compared to the control group. However , there was no statistically significant difference in duration of 2nd stage of labour in both the groups. Majority of the patients in the study group had vaginal delivery as compared to the control group. Tramadol proved to be a good labour analgesic as majority of patients had moderate pin relief when the drug was given in active labour. With regard to neonatal outcome none of the baby from the study group had respiratory depression or required NICU admission. The side effects observed were only minor side effects observed in 19% of cases. Thus the study concludes that use of drotaverine and tramadol for pain relief and acceleration of labour is simple,easy and effective method of painless and safe delivery. The analgesia produced is quite effective and overall duration of labour is significantly reduced. Both these drugs have very minimal side effects and are safe for both mother and the fetus.

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