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A Comparative Study on the Efficacy of Drotaverine Hydrochloride and Valethamate Bromide on Cervical Dilatation in Active Phase of Labour in Tertiary Care Hospital

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Abstract: ***Background: This study was conducted to compare the efficacy of Drotaverine Hydrochloride and Valethamate Bromide on cervical dilatation in active labour, and adverse effects on maternal and fetal outcome. A total number of 300 parturients were studied Group I Control Group-Received no drugs Group II Received intravenous Drotarverine hydrochloride at 3-4 cms cervical dilatation at 2 hourly intervals upto a maximum of 3 doses Group III Received intravenous Valethamate bromide at 3-4 cms cervical dilatation at hourly intervals upto a maximum of 3 doses. Mean duration of active phase of labour in control group was 183.58 ± 72.28 minutes. The duration of active phase is reduced by 96.81 minutes (52% reduction) in Drotaverine group which is statistically significant (p = 0.001) compared with control and 24.58 minutes faster than Valethamate. There was significant difference in rate of Cervical dilatation between the control and other 2 groups (p = 0.001) with Drotaverine achieving 2.72cm/ hr faster dilatation and Valethamate achieving 1.55cm/hr faster dilatation compared to control. Both Drotaverine Hydrochloride and Valethamate had no effect on the uterine contractions. The mean first injections to Delivery interval is significantly reduced in both groups given drugs 48% reductions with Drotaverine and 36% reduction with Valethamate compared to the Active phase delivery internal in Control (p = 0.001). There was no significant shortening of II stage of labour. There was no increase in incidence of instrumental delivery or abdominal delivery in either Drotaverine or Valethamate groups. The incidence of cervical tears was 2% in both drug groups. No case of atonic PPH noted in all 3 groups. Incidence of maternal side effects with drotaverine (3%) is significantly less compared to Valethamate (8%). There was no significant increase in incidence of meconium stained liquor in the drug groups compared to control. All newborns in all 3 groups had Apgar score > 7 at 5 minutes. There was no intrapartum or early neonatal deaths in all the study groups. Conclusion: Drotaverine hydrochloride is a superior cervical dilatation agent significantly reducing the duration of labour without any ill effects on the mother or the fetus. It is significantly better than Valethamate bromide with less side effects due to selective action. Hence it is recommended that Drotaverine Hydrochloride may be given to low risk women in active labour. The promising beneficial effects of Drotaverine hydrochloride are available in obstetric practice and in this study, it has definitely proven to shorten the duration of labour and provide early relief from distress for the labouring woman.***

Keywords: cervical dilatation,, active phase

1. Introduction

Labour is defined as painful uterine contraction that brings about demonstrable effacement and dilatation of the cervix. It is not a pathological process rather it is complex physiological and psychological process with acute pain. Labour is completed within 12-14hrs in about 80% of nulliparous women, whereas it is usually shorter in multipara. It is considered to be prolonged if delivery of the fetus is not completed within 24hrs.

The aim of active management is to reduce the total duration of labour without causing any adverse effects to the mother and fetus. Uterine activity and the rate of cervical dilatation are the two basic factors that determine the duration of labour. Many times it is observed that despite of good uterine contraction, cervix fails to dilate or dilates very slowly and is known as functional cervical dystocia. Methods that aim at minimizing the incidence of functional cervical dystocia and cutting short the first stage of labour are welcomed by both the obstetrician and women. Various drugs like antispasmodics, transquilizers, prostaglandins and psychotherapeutics measures have been tried over the last few decades which accelerate labour either by increasing uterine activity or by accelerating cervical dilatation. But majority of these were found to have ill effect on both the mother and fetus. The present study was done to compare the efficacy of Drotaverine hydrochloride and Valethamate bromide on cervical dilatation in active labour in relation to a control group.

2. Materials &Methods

Selection Criteria:

Inclusion Criteria

1) Term pregnancy in active labour-initial cervical dilation of 3-4 cms and cervical effacement 75%.
2) Vertex presentation
3) No cephalopelvic disproportion
4) No high risk factors
5) Labour was accelerated with oxytocin whenever needed.

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6) All the patients were managed actively

Exclusion Criteria

1) Medical disorders complicating pregnancy
2) Obstetric complications within high risk category
3) Malpresentation
4) Women with previous caesarian section

The patients were divided into 3 groups of 100 patients
Group I- Control Group-Normal labour patients-100 Nos. 31
Group II- Patients who received Inj. Drotaverine Hydrochloride-100 Nos
Group III- Patients who received Inj. Valethamate Bromide-100 Nos.

Primigravidae and multigravidae who fulfilled the above criteria were assigned Group I, Group II, Group III as they arrived, after obtaining an informed consent.

History

A detailed history regarding age, parity, socioeconomic status, occupation, booking, gestational age, H/o. any medical disorders or high risk factors was elicited.

Clinical Examination

A thorough general examination was done followed by detailed obstetric examination to know the height of fundus, presentation and position of the fetus, fetal heart sounds with respect to rhythm, rate and intensity. Vaginal examination was done in detail to know the position, effacement and dilation of cervix, position and station of presenting part, presence or absence of membranes, and for assessment of pelvis and cephalopelvic disproportion.

Management

Patients were selected randomly and were allotted to 1 of following groups, regardless of age and parity.

Group I-Control Group

Group II- Received 1 ampoule of Drotaverine Hydrochloride 40 mg intravenously at 2 hourly intervals up to a maximum of 3 doses, starting at 3-4 cms cervical dilatation.

Group III- Received, 1 ampoule of Valethamate bromide 8mg intravenously at hourly intervals up to a maximum of 3 doses, starting at 3-4 cms cervical dilatation.

Per vaginal examination was carried out usually at an interval of 2 hours and findings noted. Artificial rupture of membranes was done soon after administration of drug at 4 cm cervical dilatation, and duration of active phase of first and second stages of labour recorded.

If desired rate of contractions were not achieved oxytocin drip was started. Mode of delivery, maternal side effects and fetal outcomes were noted and tabulated. Appropriate non-parametric tests, Chisquare test and analysis of variants (ANOVA) were applied for assessment of statistical significance.

3. Discussion

In the present study, Drotaverine hydrochloride and Valethamate bromide were given intravenously at 3-4cms cervical dilatation in 2 groups of demographically similar women with term pregnancy in active labour, and compared with a control group.

It was noted that the mean duration of active phase of labour in control group was 183.58 ±72.28 minutes, and 86.77 ± 39.82 minutes in Group II and 111.35 ±43.32 minutes in Group III. In the present study, the decrease in mean duration of Active phase is 96.81 minutes in Drotaverine group compared to control, and 24.58 minutes compared with Valethamate.

The rate of cervical dilatation was 2.37 ±1.04 cm/hr in Group I, 5.09 ±2.3cm/hr in Group II, and 3.92 ±1.72 cm/hr in Group III respectively. The mean first injection delivery internal with Drotaverine is 106.61 ±43.96 minutes and 131.65 ±45.1 minutes with Valethamate. The average duration of II stage of labour was not affected by administration of drugs compared to control group.

93% cases in Drotaverine group required single injection, while 69% cases required single injection and 39% required 2 or more injections in Valethamate group. The incidence of side effects was 3% with Drotarverine compared to 8% with Valethamate. Cervical tears were noted in 2% in both drug groups. No case of atonic PPH was noted in all 3 groups. Regarding mode of delivery, in control group, 4 cases were delivered by outlet forceps and 3 cases by LSCS. In Drotaverine group, 2 cases were delivered by outlet forceps, and in Valethamate group 2 were delivered by outlet forceps and 1 by LSCS. Thus there was no increase in instrumental delivery in either of the drug groups.

Regarding fetal outcome, thin meconium stained liquor was noted in 8%, 5% and 7% of cases in Group I, II and III respectively. All were NST reactive, delivered vaginally, and had Apgar > 7/10 at 5 minutes. Thick meconium was noted in 4 cases in control group-2 delivered by LSCS, 1 by outlet forceps and 1 delivered vaginally. Thick meconium noted in 2 cases in Drotaverine group were delivered vaginally, and of the 3 cases of thick meconium in Valethamate group, 1 was delivered by LSCS and 2 by outlet forceps. All cases of thick meconium in all 3 groups were NST reactive and had Apgar > 7/10 at 5 minutes. There was no intrapartum or early neonatal deaths in all 3 groups.

4. Conclusion

Drotaverine hydrochloride is a superior cervical dilatation agent significantly reducing the duration of labour without any ill effects on the mother or the fetus. It is significantly better than Valethamate bromide with less side effects due to selective action. Hence it is recommended that Drotaverine Hydrochloride may be given to low risk women in active labour.

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The promising beneficial effects of Drotaverine hydrochloride are available in obstetric practice and in this study, it has definitely proven to shorten the duration of labour and provide early relief from distress for the labouring woman.

Table 1: Distribution of Cases according to Age Group

Age in Years	Group 1 (N=100)	Group II (N=100)	Group III (N=100)	Percentage
15-20	24	31	22	25.90%
21-25	49	56	57	54%
26-30	23	13	19	18.30%
31-35	4	0	2	2%

X2=8.21 P=0.16 (Not Significant)

Patients in age group of 21-30 years contributed to 72.3%.

Table 2: Distribution of Cases according to Gravidity

Parity	Group 1 (N=100)	Group II (N=100)	Group III (N=100)	Percentage
PRIMI	50	50	50	50%
GRAVIDA 2	31	38	34	34.30%
GRAVIDA 3	16	8	12	12%
GRAVIDA 4&5	3	4	4	3.67%

X2 =3.57. P=0.74 (Not significant)

Table 3A: Duration of Active Phase of Labour in Different Groups in Primigravidae

Group	No. of Cases	Mean Duration (min)	Difference of means (min)	Difference in percentage
I	50	203.4		
II	50	94.6	108.8	53%
III	50	118.6	84.8	41%

Drotaverine Hydrochloride shortened the mean duration of active phase of labour in primigravidae by 108.8 minutes (53% reduction) and Valethamate Bromide by 84.8 minutes (41% reduction) compared to control group.
F = 312.64, (P = 0.001)-Statistically Significant.

Table 3B: Duration of Active Phase of Labour in Different Groups in Multigravidae

Group	No. of Cases	Mean Duration (min)	Difference of means (min)	Difference in percentage
I	50	163.76		
II	50	78.94	84.82	57%
III	50	104.1	59.66	36%

Drotaverine hydrochloride shortened the duration of active phase of labour in multigravidae by 84.82 minutes. (57% reduction) and Valethamate Bromide by 59.66 minutes. (36% reduction) compared to control.

F = 159.35, P = 0.001-Statistically Significant.

Table 4A: Rate of Cervical Dilatation in Active Phase in Primigravidae

Group	No. of Cases	Average rate of cervical dilatation (cm/hr)	Difference of Means (cm/hr)
I	50	2.09	
II	50	4.59	2.5
III	50	3.64	1.55

Drotaverine hydrochloride increased the average rate of cervical dilatation by 2.5 cm/hr in primigravidae, and Valethamate bromide by 1.55 cm/hr compared to control group.

F = 196.26, P = 0.001-Statistically Significant.

Table B: Rate of Cervical Dilatation in Active Phase in Multigravidae

Group	No. of Cases	Average rate of cervical dilatation (cm/hr)	Difference of Means (cm/hr)
I	50	2.65	
II	50	5.58	2.93
III	50	4.2	1.55

Drotaverine Hydrochloride increased the average rate of cervical dilatation by 2.93 cm/hr in multigravidae and Valethamate bromide by 1.55 cm/hour compared to control group.
F = 118.67 P = 0.001-Statistically Significant.

Table 5 A: Duration of II Stage of Labour in Primigravidae

Group	No. of. cases	Mean Duration (minutes)	Difference of means (minutes)
I	50	25.3	
II	50	19.62	2.68
III	50	21.08	1.22

There was no significant shortening of II stage of labour with either Drotaverine Hydrochloride or Valethamate Bromide in primigravidae in all 3 groups.

F = 1.23, P = 0.15, Not significant.

Table 5 B: Duration of II Stage of Labour In Multigravidae

Group	No. of. cases	Mean Duration (minutes)	Difference of means (minutes)
I	50	20.68	
II	50	18.86	1.82
III	50	19.82	0.86

The duration of second stage of labour is not significantly different in the 3 groups in multigravidae also.
F = 1.53, P = 0.23, Not significant.

Table 6 A: Active Phase / First Injection Delivery Interval in Primigravidae

Groups	Gravidity	Active phase First Injection-Delivery Interval (minutes)	Difference of Means (Minutes)	Difference in Percentage
Group I	Primigravidae	225.7		
Group II	Primigravidae	114.62	111.08	49%
Group III	Primigravidae	139.78	85.92	38%

The mean first injection delivery interval was shortened by Drotaverine Hydrochloride in primigravidae by 111.08 mts (49% reduction) and with Valethamate Bromide by 85.92 mts (38% reduction) compared to active phase –delivery interval in control group.

P = 0.001, Statistically Significant.

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Table 6B: Active Phase / First Injection Delivery Interval in Multigravidae

Groups	Gravidity	Active phase First Injection-Delivery Interval(minutes)	Difference of Means (Minutes)	Difference in Percentage
Group I	Multigravidae	184.44		
Group II	Multigravidae	98.6	85.84	96.50%
Group III	Multigravidae	123.52	60.92	33%

The first injection delivery interval was shortened by Drotaverine in mutigravidae by 85.84 minutes (46.5% reduction) and with Valethamate by 60.92 minutes (33% reduction) compared to active phase delivery interval in control group.
P = 0.001, Statistically Significant

Table 7: Oxytocin Augmentation

Oxytocin	Group I	Group II	Group III
Used	52%	46%	48%
Not Used	48%	54%	52%

52%, 46% and 48% required oxytocin augmentation in groups I, II and III respectively. Hence both Drotaverine Hydrochloride and Valethamate Bromide had no effect on uterine contractions.

Table 8: Character of Amniotic Fluid

Type of liquor	Group I	Group II	Group III	Fetal Outcome
Clear	89	93	90	Good
Thin Meconium	7	5	7	Good
Thick Meconium	4	2	3	Good

Patients with thin meconium stained liquor in all three groups were NST Reactive, delivered vaginally and had Apgar > 7/10 at 5 minutes.

All cases of thick meconium were NST Reactive. In control group, 2 were taken up for LSCS, 1 delivered by outlet forceps and 1 delivered vaginally; all had Apgar > 7/10 at 5 minutes.

In Drotaverine group both delivered vaginally-one as face to pubis. Both were vigorous babies and had Apgar > 7/10 at 5 minutes.

In Valethamate group 1 was delivered by LSCS and 2 by outlet forceps. All had Apgar > 7/10 at 5 minutes.

Table 9A: Mode of Delivery in Primigravidae

Group	No. of Cases	Normal vaginal delivery	Forceps delivery	LSCS
I	50	46	2	2
II	50	49	1	0
III	50	48	1	1

There was no increase in instrumental delivery in either of the groups given Drotaverine or Valethamate in Primigravidae. Indications for LSCS in control group were fetal distress and secondary arrest of cervical dilation. Indications for LSCS in drug groups were not pertaining to drug administration.

X2 = 6.18 P = 0.19 Not Significant

Table 9B: Mode of Delivery in Multigravidae

Group	No. of Cases	Normal vaginal delivery	Forceps delivery	LSCS
I	50	47	2	1
II	50	49	1	0
III	50	49	1	0

There was no increase in instrumental delivery in either of the groups given Drotaverine or Valethamate in multigravidae. Indication for LSCS in group I was fetal distress. Indications for outlet forceps in all groups were failure of secondary powers.

X2 = 6.12 P = 3.19 Not significant

Table 10: Relationship between Drugs and Fetal Outcome

Group	No. of cases	APGAR SCORE			
		1 minute		5 minutes	
		<7/10	>7/10	<7/10	>7/10
I	Primi-50	2	48	0	50
	Multi-50	2	48	0	50
II	Primi-50	1	49	0	50
	Multi-50	2	48	0	50
III	Primi-50	3	47	0	50
	Multi-50	0	50	0	50

3% of newborns in all the 3 groups had Apgar score of < 7 at birth (1mt) and 1 newborn in control group required observation in NICU for 2 hours. All the newborns in all the 3 groups had Apgar score of > 7 at 5 minutes. There was no intrapartum or early neonatal deaths in all the study groups.
X2 = 0.5 P = 0.568 Not significant

Table 11: Third Stage Complications

Complications	Drotaverine Group	Valethamate Group	Control
Cervical tears	2%	2%	0%
Atonic PPH	0%	0%	0%

Cervical tear was noted in 2% of cases in Group I and Group II. No case of postpartum hemorrhage was observed in any woman.

Table 12: Comparison of Number of Injections given in the different groups

Group	No. of cases	No. of. Injections			
		1		>/=2	
Group II	100	Primi (49)	93%	Primi (1)	7%
		Multi (44)		Multi (6)	
Group III	100	Primi (24)	61%	Primi (26)	39%
		Multi (37)		Multi (13)	

The number of injections required in both groups was limited to 3; single injection was required in 93% cases in Group II, while in Group III 61% cases required single injection and 39% cases required 2 or more injections.

X2 =28.91 OR=8.5 95%CI=3–22 P = 0.001 Statistically significant

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Table 13: Untoward Maternal Effects after Drotaverine Hydrochloride and Valethamate Bromide

Side effects	Group II	Dose of drug in mg	Group III	Dose of drug in mg
Dryness of mouth	1	80	4	16
Vomiting	1	80	1	24
Tachycardia	1	80	3	16

In Drotaverine group, 3% exhibited side effects while in the Valethamate group 8% exhibited side effects. Most common side effects in Valethamate group were dryness of mouth and tachycardia. In both groups side effects were noted after two or more injections hence they are dose related.

Table 14: Tests of Statistical Significance

	Group I	Group II	Difference of Means (minutes)	%	Group III	Difference of means (minutes)	%	Anova Test P value& Significance
No. of cases	100	100		100				
Mean Duration of Active Phase (minutes)	183.58+/-72.28	86.77+/-39.83	96.81	52%	113.35+/-43.32	70.23	38%	F=34.77, P=0.001, Significant
Mean rate of cervical dilatation (cm/hr)	2.37+/-1.04	5.09+/-2.3	2.72		3.92+/-1.72	1.55		F=236.44, P=0.001, Significant
Mean Active phase/Drug-Delivery interval (minutes)	205.07+/-75.66	106.61+/-43.96	98.46	48%	131.65+/-45.1	73.42	36%	F=332.86, P=0.001, Significant

Thus Drotaverine hydrochlomide and Valethamate bromide achieved 52% and 38% reduction in mean duration of active phase of labour respectively compared with control group. The mean rate of cervical dilatation was 2.72 cm/hr faster with Drotaverine and 1.55 cm/hr with epidosin compared to control. The mean drug delivery interval was 48% shortened by Drotaverine and 36% shortened by Valethamate compared to Active phase Delivery interval of Control group.

Table 15: Comparison of Maternal and Fetal Outcomes

Outcome		Group I	Group II	Group III
Mode	Vaginal	93	98	97
	Outlet forceps	4	2	2
	LSCS	3	0	1
Cervical tears		0	2%	2%
Atonic PPH		0	0	0
Meconium stained liquor		12%	7%	10%
Maternal side effects		4%	3%	8%
APGAR<7/10 at 1 min		3%	3%	3%
APGAR >7 at 5 min		100%	100%	100%

Drotaverine hydrochloride and Valethamate Bromide compared favourably with each other with respect to maternal and fetal outcomes, except that Valethamate had a higher incidence of maternal side effect.

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