

A Hospital Based Prospective Study to Compare the Efficacy of Drotaverine Hydrochloride and Valethamate Bromide on Cervical Dilatation in Active Labour at Tertiary Care Center

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Abstract

Background: Labor is the most perilous journey a woman has to undertake. 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. **Materials & Methods:** This was a prospective study conducted in a tertiary center over a span of 12 months period. 150 patients were randomly allotted in 3 groups. 50 patients-control group, 50 patients- Injection Drotaverine and 50 patients - Injection Valethamate bromide. All these patients were entered into partograms and the progress of labour, uterine contractions and the fetal heart rate were monitored carefully. Appropriate non-parametric tests, X2 test and analysis of variants (ANOVA) were applied for assessment of statistical significance. **Results:** Our study showed that maximum no. of patients (73%) in 21-30 years of age groups. In all the three groups both primigravida and multigravida were included, but not statistical significant ($P>0.05$). The present study showed that both the drugs shorten the duration of first stage of labor when compared to control, but Drotaverine reduces the duration more than Valethamate bromide. Both in primi and multi this difference was statistically significant. **Conclusion:** We conclude that effect of Drotaverine on shortening duration of labour is significantly better than Valethamate with fewer side effects. Thus, Drotaverine is a safe, potent and effective drug to shorten the first stage of labour.

Keywords: Primigravida, Multigravida, Labor, Drotaverine, Valethamate.

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Introduction

Labour is a natural physiological phenomenon of childbirth. It is a multifactorial spontaneous process which involves myometrial contractions, cervical ripening and dilatation, and expulsion of the fetus and placenta in an orderly manner. Labour is defined as painful uterine contraction that bring about demonstrable effacement and dilatation of the cervix[1]. The driving forces of uterine contraction act upon the cervix which plays the role of innocent obstruction due to passive tissue resistance. It has been proved that cervical dilatation is one of the important factors which determine the duration of labour. 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[2]. Uterine activity and the rate of cervical dilatation are the two basic factors that determine the duration of labour. Sometimes it is observed that although uterine contractions are good, the cervix fails to dilate or dilates very slowly or partially. The most common cause of prolonged first stage of labour is cervical spasm due to the overactivity of the

circular muscle fibres of cervix, which may be increased in presence of inflammation injury or fibrosis of cervix or due to fear tension pain syndrome. Prolonged labour results in maternal exhaustion.

Various drugs like antispasmodics, tranquilizers, 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[3,4]. But majority of these were found to have ill effect on both the mother and fetus. Valethamate bromide is one of the drug of esocin group which have neurotropic and musclotropic actions that results in relaxation of cervical musculature leading to quick dilatation of the cervix and shortens labour[5,6]. Recently a new drug, Drotaverine hydrochloride, an isoquinoline used primarily to relieve gastrointestinal and renal colics has been tried and found to be effective in reducing the duration of dilatation stage of labour with excellent results[7,8]. Drotaverine hydrochloride and Valethamate bromide exert their main effect on the cervix, facilitating its dilatation and can only be used for augmentation of labour in women with established labour preferably with 4 cm dilatation of cervix and good uterine contractions. We chose these two drugs to ascertain their role in augmentation of labour as to whether they can be recommended in routine use.

Active management of labour was introduced into clinical practice in 1963 at National Maternity Hospital, Dublin. It's aim was to reduce maternal and fetal distress, shorten the duration of labour and anticipation and management of complications. Cervical smooth muscle relaxants are well accepted addendum to the principle of

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active management of labour. 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.

Materials & methods

This was a prospective study conducted in a tertiary center over a span of 12 months period. 150 patients were randomly allotted in 3 groups.

1. 50 patients (25 primigravida and 25 multigravida)- control group
2. 50 patients (25 primigravida and 25 multigravida) – Injection Drotaverine
3. 50 patients (25 primigravida and 25 multigravida) – Injection Valethamate bromide

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. Period of gestation > 28 weeks
5. Primigravida and multigravida
4. No high-risk factors
5. Labour was accelerated with syntocinon whenever needed.
6. All the patients were managed actively

Criteria for exclusion from study

1. Non cephalic presentation
2. Multiple pregnancy
3. Known hypersensitivity to Drotaverine or Valethamate bromide
4. Trial of labor
5. Medical disorders complicating pregnancy
6. Obstetric complications within high-risk category
7. Women with previous caesarian section

Methods

The patients fulfilling the above criteria were included in the study. An informed written consent was obtained from all the mothers and were divided into 2 groups.

Group D (Drotaverine group): Patients in this group were given injection Drotaverine 40 mg (2ml) intramuscularly at 3 cm dilatation

Results

Our study showed that maximum no. of patients (73%) in 21-30 years of age groups (table 1).

Table 1: Distribution Of Cases According To Age Group

Age groups	Group C (N=50)	Group D (N=50)	Group V (N=50)	Percentage
15-20 yrs	12	15	10	24.66%
21-25 yrs	25	28	29	54.66%
26-30yrs	11	7	10	18.66%
31-35 yrs	1	0	1	2%

In all the three groups both primigravida and multigravida were included, but not statistically significant ($P>0.05$) (table 2).

Table 2: Distribution Of Cases According To Gravidity

Gravidity	Group C (N=50)	Group D (N=50)	Group V (N=50)	P-value
Primigravida	32	28	30	>0.05
Multigravida	18	22	20	>0.05

Drotaverine hydrochloride increased the average rate of cervical dilatation by 2.43 cm/hr in primigravidae, and Valethamate bromide by 1.69 cm/hr compared to control group in primigravida. The average rate of cervical dilatation by 2.86 cm/hr in multigravidae and Valethamate bromide by 1.52 cm/hour compared to control group, which was statistically significant (Table 3).

Table 3: Rate Of Cervical Dilatation In Active Phase In Primigravidae and multigravida in three groups

Gravidity	Average rate of cervical dilatation (cm /hr)			P-value
	Group C (N=50) mean value	Group D (N=50) mean value	Group V (N=50) mean value	
Primigravida	2.03	4.46	3.72	<0.001
Multigravida	2.66	5.52	4.18	<0.001

Analysis of variants (ANOVA)

Drotaverine Hydrochloride shortened the mean duration of active phase of labour in primigravidae by 108.23 minutes (53% reduction) and Valethamate Bromide by 84.9 minutes (41% reduction) compared to control group. The duration of active phase of labour in multigravidae by 84.93 minutes. (57% reduction) and Valethamate Bromide by 59.36 minutes. (36% reduction) compared to control, which was statistically significant (Table 4).

of cervix. Dose was repeated at an interval of 2 hours till full dilatation of cervix. Maximum of 3 doses were given.

Group V (Valethamate group): Patient in this group were given injection Valethamate 8 mg intramuscular at 3 cm dilatation of cervix. Dose was repeated at an interval of 1 hour till full dilatation of cervix. Maximum of 3 doses were given.

Group C (Control group): This group included 50 patients and no drug was given.

Details of the mothers were recorded on a prestructured proforma which include detail history of present pregnancy, menstrual history, obstetric history and any significant past history were recorded. Complete general and systemic examination was done and findings were recorded. Obstetrical examination including fundal grip, lateral grip, first and second pelvic grip were done to ascertain the number of fetus, lie and presentation.

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

All these patients were entered into partograms and the progress of labour, uterine contractions and the fetal heart rate were monitored carefully.

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. Standard parameters for maternal and fetal well being was monitored as specified by Dawn. 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.

Statistical Analysis

Appropriate non-parametric tests, X2 test and analysis of variants (ANOVA) were applied for assessment of statistical significance.

Table 4: Duration Of Active Phase Of Labour In Primigravidae And Multigravida In Three Groups

Gravidity	Duration Of Active Phase Of Labour (min.)			P-value
	Group C (N=50) mean value	Group D (N=50) mean value	Group V (N=50) mean value	
Primigravida	202.80	94.57	117.9	<0.001
Multigravida	164.59	78.66	105.23	<0.001

Analysis of variants (ANOVA)

The mean first injection delivery interval was shortened by Drotaverine Hydrochloride in primigravidae by 110.07 mts (49% reduction) and with Valethamate Bromide by 85.81 mts (38% reduction) compared to active phase – delivery interval in control group. The first injection delivery interval was shortened by Drotaverine in multigravidae by 84.94 minutes (46.5% reduction) and with Valethamate by 59.48 minutes (33% reduction) compared to active phase delivery interval in control group (table 5).

Table 5: Active Phase / First Injection Delivery Interval In Primigravidae And Multigravida In Three Groups

Gravidity	Active Phase / First Injection Delivery Interval (Min.)			P-value
	Group C (N=50) mean value	Group D (N=50) mean value	Group V (N=50) mean value	
Primigravida	224.6	114.53	138.79	<0.001
Multigravida	183.7	98.76	124.22	<0.001

Analysis of variants (ANOVA)

Discussion

In the developing world prolonged and often neglected labour is associated with high rates of maternal infection, obstructed labour, uterine rupture and postpartum haemorrhage which may all end in maternal mortality. Improper estimation of time duration of normal labour may also lead to morbidity, mortality or disability of the newborn.

The mean age in control group was of 24.28+1.42 years while 24.16+1.7 and 24.33+1.66 years of those in Valethamate and Drotaverine group respectively. In a study conducted by Tripti N and Jyoti J (2009)[9] mean age in Valethamate group was 23.25 years and in Drotaverine group mean age was 22.76 while In another study by Thapa M, et al(2007)[10] mean age in valethamate group was 23.3 years and in Drotaverine group was 22.8years.

It was noted that the mean duration of active phase of labour in control group was 184.47 ± 70.18 minutes, and 88.27 ± 38.82 minutes in Group II and 110.35 ± 43.22 minutes in Group III. The results were comparable with similar study done by Anju Huria et al[11].

Palii SB et al (2013)[12] also found the mean duration of Active phase of First stage of Labor to be less in women given Drotaverine (186.3mins in Primigravida& 140.76mins in Multigravida) compared to the Valethamate group (254.2mins in Primigravida&172.82mins in Multigravida).

The results of another study done by Roy A et al[13] in 2007 were similar showing the mean duration of Active phase of First stage of Labor in Primigravida to be 148.9mins, 331.6mins in Drotaverine and Control group respectively. In Multigravida, the mean duration of Active Labor was 99.5mins,227.9mins in Drotaverine and Control groups respectively.

Tripti N and Jyoti J(2009)⁹ observed higher rate of cervical dilatation in their study. Thus the rate of cervical dilatation was higher in drotaverine group as compared to control and Valethamate group. Duration of active phase of 1st stage in Valethamate group was 179.6+24.2mins, in Drotaverine group it was 145.3+1.7mins and in control group it was 289.7+3.6mins. Tripti N and Jyoti J(2009)²⁰ observe that the duration of active phase of 1st stage in Valethamate group was 177.4 minutes and in Drotaverine group was 113.5minutes. In study by Anju Huria et al, both Valethamate and Drotaverine caused highly significant reduction in duration of first stage as compared to control in nulliparous as well as in multiparous (p<0.01). Valethamate was significantly more effective than Drotaverine in nulliparous(p<0.001) but not so in multiparous[11]. In our study both Valethamate and Drotaverine caused significant reduction in the duration of early active phase of labour irrespective of parity. Drotaverine was significantly more effective than Valethamate (p<0.001).

In study of J.B sharma mean injection to delivery interval was 220.07 ± 86.12min and 194 ± 57.04 min respectively[14]. There was significant difference when two study groups were compared, which was compatible with our results.

Conclusion

We conclude that effect of Drotaverine on shortening duration of labour is significantly better than Valethamate with fewer side effects. Thus, Drotaverine is a safe, potent and effective drug to shorten the first stage of labour.

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