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Original Research Article

Comparison of efficacy of Drotaverine hydrochloride and Valethamate bromide in the augmentation of labour: a hospital based randomized trial

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ABSTRACT

Background: Labour is a process of contraction with the goal of producing progressive cervical effacement and dilatation in order to expel the uterine foetus from the intrauterine to the extra-uterine environment. The objective of this study was to compare the efficacy and safety of drotaverine hydrochloride and valethamate bromide for shortening the duration of labour.

Methods: This randomized trial was conducted at R. G. Kar Medical College over one year. Total 360 primigravida or multigravidae mothers satisfying the criteria of having singleton term pregnancy with cephalic presentation with spontaneous onset of labour were included and allocated randomly into Drotaverine Group (Group 1) and Valethamate Group (Group 2).

Results: There was statistically significant reduction of mean duration of first stage of labour both in primigravida (123.12±37.82 min versus 156.30±45.10 min) and multigravidae (102.75± 36.90 min versus 139.98±45.89 min) in Group 1 than Group 2. P value <0.0001 in each Group. The mean rate of cervical dilatation in Group 1 was 3.0±0.41 cm/hr and 3.5±0.414 cm/hr in primigravida and multigravidae respectively. 2.67±0.51 cm/hr in primigravida and 2.90±0.44cm/hr in multigravidae in Group 2. It was statistically significant (p<0.0001 in both Groups). Mean injection to delivery interval both in primigravida and multigravidae of Group 1 were significantly less than Group 2 (p=0.0006 and p<0.0001 respectively). Modes of delivery were comparable in both Groups (p=0.756). Few maternal complications like transient tachycardia was more (12) in VB Group in compare to DH (3). Although it was not statistically significant (p=0.268). Foetal complications including Apgar score at 1 min and 5 min in both Groups were comparable in both primigravida and multigravidae (P value 0.39718 and 0.285 respectively).

Conclusions: Drotaverine hydrochloride has promising beneficial effects on labour and it is safe to use.

Keywords: Drotaverine hydrochloride, Labour, Valethamate bromide

INTRODUCTION

Labour is a process of contraction with the goal of producing progressive cervical effacement and dilatation in order to expel the uterine foetus from the intrauterine to the extra-uterine environment.¹ Labour mostly sets in spontaneously but for various obstetrical and medical

indications it needs to be induced when the benefits to either the mother or the foetus outweigh those of continuing the pregnancy.² Unduly prolonged labour is likely to give rise to 3 types of distress maternal, foetal or obstetrician and the last may be most dangerous. Prolonged and painful labour is not only a cause of mental anguish but also maternal and foetal morbidity

and mortality due to increased risks of maternal exhaustion, postpartum haemorrhage and sepsis, fetal distress and asphyxia and requires early detection and appropriate clinical response.³ The risks for complications of prolonged labour are much greater in poor resource settings.⁴ Augmentation of labour is used to treat delayed labour when poor uterine contractions are the underlying cause. The traditional methods of labour augmentation is the use of oxytocin infusion and artificial rupture of the membranes (amniotomy).⁵ Over the last few decades, efforts to avoid prolonged labour in institutional birth have led to the use of a range of practices to either accelerate slow labour or drive the physiological process of normally progressing labour. While interventions with augmentation of labour may be beneficial, their inappropriate use can cause harm. Sedatives and belladonna alkaloids have been tried to hasten cervical dilatation, but many have adverse effects on mother and fetus.⁵ Spasmolytics and spasmolytics mixtures are administered to facilitate dilatation of the cervix during delivery and to shorten first stage of labour.⁶ An ideal antispasmodic for accelerations of cervical dilations should have a prompt and long lasting action, no adverse effects on uterine contractility and be free from risk of uterine inertia. It should also have minimal side effects in the mother and foetus.⁵

Application of antispasmodics in obstetrics to relieve cervical spasm was first introduced by Von Kries and his pupils in 1923. Today the advent of various forms of pharmacological interventions have helped in shortening the duration of labour either by augmenting uterine contractions or by accelerating the rate of cervical dilatation.⁷ Drotaverine is an isoquinoline derivative which binds to the surface of smooth muscles and changes their membrane potential and permeability. It inhibits phosphodiesterase IV enzyme which breaks cAMP and cGMP which play an important role in regulation of smooth muscle tone.⁴ It acts specifically on spastic sites and corrects the cAMP and calcium imbalance relieving smooth muscle spasm.⁸ Valethamate bromide or epidosisin is from the group of 'Efosin' described by Steinmann (1954) for use in hastening labour.⁹

It is an ester with quaternary N atom, which by virtue of its anticholinergic, parasympatholytics and musculotropic action relieves spasm of smooth muscle of cervix. These two drugs are used for cervical dilatation in modern obstetrics without deleterious effects on mother/fetus.⁸ In this era where the focus is shifting from 'wait and watch' policy to 'active intervention sooner than later to ensure better labour outcomes, these drugs use in synergy with analgesics enable modern obstetricians to make labour and delivery a safe and pleasant experience for the mother.

The goal of the present study was to compare the efficacy and safety of drotaverine hydrochloride and valethamate bromide for shortening the duration of labour.

METHODS

The present study was conducted in the labour room complex in the department of Gynaecology and Obstetrics, R. G. Kar Medical College and Hospital from 1st July 2014 to 30th June 2015.

Present study was a prospective open-label randomized trial. Study population was drawn from antenatal mothers admitted to R. G. Kar Medical College and Hospital for delivery.

The study population comprised of two groups:

- Drotaverine hydrochloride group
- Valethamate bromide group.

Study variables

Independent variables

- Age
- Religion
- Socio-economic status
- Residence
- Gravid

Dependent variables

- Duration of 1st stage of labour
- Injection to delivery interval
- Rate of cervical dilatation
- Number of injection required
- Rate of caesarean delivery
- Instrumental vaginal birth
- Dryness of mouth and vomiting
- Transient tachycardia
- Vomiting
- Retention of urine
- PPH
- Postpartum fever
- Birth asphyxia
- Meconium aspiration syndrome
- APGAR Score at 1min. and 5min
- Neonatal sepsis

Inclusion criteria

- Live singleton pregnancy at term
- Both primigravida and multigravidae
- Cephalic presentation
- Spontaneous onset of labour

Exclusion criteria

- Ruptured membranes
- Cervical dilatation >4 cm at admission
- Multiple gestation

- Non-cephalic presentation
- Prior caesarean delivery
- Grand multipara
- Cephalopelvic disproportion
- Previous h/o cervical surgery
- Preterm
- Hypertensive disorder

Sample size

A total of 360 women were randomized to drotaverine group and Valethamate group, 180 in each arm was needed to show a difference of 30 minutes mean injection delivery interval with use of injection drotaverine hydrochloride at 80% power and an alpha error 0.05. With these assumptions in mind, we had taken 180 subjects per group which would be sufficient.

Sampling design

Allocation

Randomized randomization was performed by computer-generated random code, created in blocks of ten at R. G. KAR G and O office in Kolkata. The code was used by employee of our college who were not part of the research team as a basis for sealing cards in consecutively numbered envelopes; the cards read either "Drotaverine hydrochloride" or "Valethamate bromide". When a new participant was enrolled in the study, site staff opened the next envelope in the numbered series and the woman had received the treatment specified there in.

End point classification

- Safety
- Efficacy
- Acceptability
- Feasibility

Arms: Patient received injection drotaverine hydrochloride. Patient received injection Valethamate bromide.

Masking: Open label

Method of data collection

Technique

This study was done after getting approval from the Institutional ethics committee of our institution and it was conducted in the Department of Obstetrics and Gynaecology, R. G. Kar Medical College and Hospital. 360 women were selected for this study after an informed consent as per parameters cited above. Women who met the above requirements were given a full description of the study and asked if they would like to participate. Those who gave written informed consent were randomly

assigned to one of the two study regimens. Women who were unable to read the consent form had the form read to them in their native language. Those who did not wish to participate were given standard treatment and care. 180 patients were allocated in each of the study groups.

Group I

Injection Valethamate was administered intravenously at an interval of 30 minutes, 1 hour up to a maximum of 6 injections.

Group II

Injection Drotaverine was administered intravenously during labour at an interval of 2 hours up to a maximum of 3 injections.

The patients were monitored for pulse rate, blood pressure, uterine contractions, progress and descent of presenting part, cervical dilatation and fetal heart sound. Maternal side effects like tachycardia, fever, dryness of mouth, nausea, vomiting was recorded.

Mode of delivery, duration of I, II, III stage of labour and fetal outcomes were recorded and compared to know the efficacy of Drotaverine and Valethamate on cervical dilatation and in shortening the duration of first stage of labour. Partograph was maintained during labour.

Tools

- Proper history taking and clinical examination
- Drugs: Drotaverine hydrochloride and Valethamate bromide
- CTG machine
- Syringe
- Thermometer
- USG facility-optional

Laboratory investigations (not mandatory)

- Routine hemogram
- Fasting blood sugar
- Post-prandial blood sugar
- Urine R/E, C/S
- Blood grouping and Rh typing
- HIV

Definition of outcome

Injection to delivery interval

Time interval between first injection to vaginal delivery.

Duration of 1st stage of labour

Time interval between onset of true labour pain to full dilatation of cervix.

Postpartum fever:

Oral temperature >38°C on two separate occasions 6 hours apart after 24 hours of delivery.

Rate of cervical dilatation

It was monitored through partograph.

Statistical analysis

Data were analysed using SPSS statistical software (SPSS Inc., Chicago, IL, USA).

Chi-square tests were used for categorical data, and z tests were used for continuous data. Statistical significance in all calculations were defined as P <0.05.

RESULTS

360 women were recruited for the trial, of which 180 mothers were recruited into Drotaverine group and 180 to Valethamate group. All the patients were available for data collection.

We have enrolled 360 mothers, 180 mothers in each group. Drotaverine hydrochloride and Valethamate bromide.

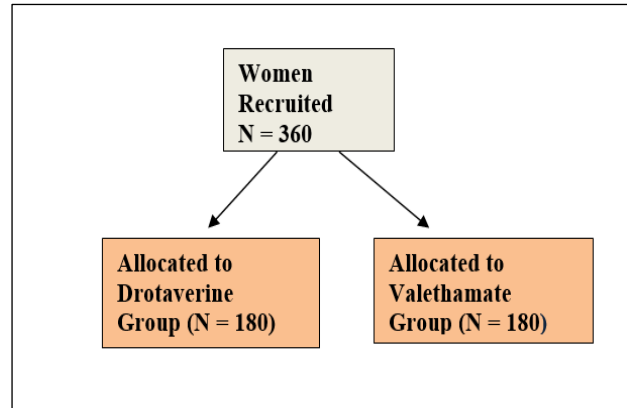


Figure 1: Consort flow chart.

Demographic profile and clinical parameters in all the patients were comparable at the start of study. There were no statistically significant differences.

Table 1: Demographic profile.

Age	No. of patients		
Age in years	DH	VB	
<20	15 (8.34%)	22 (12.22%)	x2 = 1.93, df = 2, p = 0.382
20-30	149 (82.78%)	146 (81.11%)	
>30	16 (8.88%)	12 (6.67%)	
Religion			
Hindu	73 (40.56%)	89 (49.44%)	x2 = 2.87, df = 1, p = 0.09
Muslim	107 (59.44%)	91 (50.56%)	
Socio-economic status			
Higher	5 (2.78%)	2 (1.11%)	x2 = 3.93, df = 2, p = 0.140
Middle	61 (33.89%)	77 (42.78%)	
Lower	114 (63.33%)	101 (56.11%)	
Residence			
Rural	127 (70.56%)	141 (78.33%)	x2 = 2.86, df = 1, p = 0.091
Urban	53 (29.44%)	39 (21.67%)	
Gravida			
Primigravida	112 (62.22%)	122 (67.78%)	x2 = 1.22, df = 1, p = 0.269
Multigravidae	68 (37.78%)	58 (32.22%)	

Table 2: Labour outcomes.

	Drotaverine Hydrochloride	Valethamate Bromide	
Duration of active phase of labour in primigravida			
<2 hours	52 (46.42%)	31 (25.40%)	P = 0.0001
2-3 hours	53 (47.32%)	52 (46.42%)	
>3 hours	07 (6.25%)	39 (34.82%)	
Mean of duration of 1 st stage of labour	123.12±37.82	156.30±45.10	P value <0.0001
Duration of active phase of labour in multigravidae			
<2hours	39 (57.35%)	22 (37.93%)	P=0.0001
2-3hours	29 (42.65%)	23 (39.66%)	
>3hours	0	13 (22.41%)	
Mean of duration of 1 st stage of labour	102.75±36.9 min	139.98±45.89mi n	P value <0.0001
Mean rate of cervical dilatation (cm/hr)			
Primigravida	3.0±0.41	2.67±0.51	P value <0.0001
Multigravidae	3.5±0.414	2.90±0.44	P value <0.0001
Mean injection to delivery interval			
Primigravida	190.92±38.96mi n	209.80±45.13mi n	P value 0.0006
Multigravidae	132.08±32.99mi n	172.86±48.35mi n	P value <0.0001
Mode of delivery			
Spontaneous vaginal delivery	165 (91.67%)	161 (89.44%)	x2 = 0.55, df = 2, P = 0.756
Instrumental	2 (1.11%)	3 (1.6%)	
LSCS	13 (7.22%)	16 (8.89%)	

Mean duration of 1st stage of labour was 123.12±37.82 min and 156.30±45.10 min in primigravida and 102.75±36.90 min and 139.98±45.89 min in multigravidae in Drotaverine and Valethamate groups respectively. P value <0.0001 in both cases.

Mean rate of cervical dilatation in primigravidae 3.0±0.41 cm/hr and 3.5±0.414 cm/hr in multigravidae in DH and 2.67±0.51 cm/hr and 2.9±0.44 cm/hr in primigravida and multigravidae in VB group respectively.

The results are statistically significant (p <0.05). Mean injection to delivery interval was less both for primigravida and multigravidae in DH group than VB group (190.92±38.96 min v/s 209.80±45.13min in primigravidae and 132.08±32.99 min v/s 172.86±48.35 min in multigravidae). Mode of delivery was comparable in both groups P = 0.756.

Table 3: Foeto-maternal outcomes.

Maternal complications				
Complications	No. of patients			
	DP	VP	DM	VM
Vomiting	7	5	3	3
Dryness of mouth	0	3	0	2
Transient tachycardia	3	12	4	9
Retention of urine	0	1	0	0
Cervical tear	1	1	0	1
Paraurethral tear	0	1	0	1
PPH	3	2	7	6
Fever	1	2	1	4
Fetal complications				
Neonatal sepsis	1	0	1	2
MAS	0	1	0	1
Birth asphyxia	1	2	0	0
Apgar score at 1 min				
Apgar score	DH	VB		
≥ 7	144 (80%)	135 (75%)	x ² = 0.7168, df = 1, p = 0.39718	
< 7	36 (20%)	45 (25%)		
Apgar score at 5 minutes				
≥ 7	162 (90%)	153 (85%)	x ² = 1.429, df = 1, P = 0.285	
< 7	18 (10%)	27 (15%)		

Maternal complications were similar in both groups except few complications like transient tachycardia and dryness of mouth were slightly more in Valethamate group, but which is not statistically significant (p=0.268). Fetal complications were comparable in both groups.

DISCUSSION

In the present study, the mean duration of active phase of labour in drotaverine group was 123.12 (±37.82) and 102.75 (±36.90) min in primigravida and multigravida respectively whereas in Valethamate group results were 156.30 (±45.10) and 139.98 (±45.89) min. There was a statistically significant reduction in the duration of active phase of labor in both primigravida and multigravida given drotaverine when compared with Valethamate bromide. Drotaverine was significantly more effective than Valethamate (p<0.0001). The results of another study done by Malaysarkar et al are similar showing the duration of active phase to be 174.7 min in primigravida and 148.2 min in multigravidae given drotaverine compared to 196 min in primigravida and 176.1 min in multigravida given valethamate bromide.¹¹

Mishra et al also found duration of active phase of labor to be less in women given Drotaverine (205 min in primigravida and 105 min in mutigravida) compared to Valethamate bromide (275 min in primigravida and 210 min in mutigravida). Present study results were very similar with results of another study done by Jayashree et al.¹³ In the present study, duration of active phase of labour was less than 2 hrs in 46.42% of primigravida and 57.35% of multigravida in drotaverine group, compared to 25.40% of primigravida and 37.93% of multigravida in Valethamate group corroborating nicely with study by Jayashree et al.¹³ Thirteen trials (n = 1995) reported on the duration of first stage of labour, which was significantly reduced by an average of 74.34 minutes when antispasmodics were administered (mean difference (MD) -74.34 minutes; 95% confidence Interval (CI) -98.76 to -49.93).¹⁴

Dahal P et al reported in their study that the mean duration of active phase of labour in group 1 (Valethamate group), 2 (Drotaverine group) was 254.29±96.621 min, 178.31±73.412 min min respectively.¹⁵ Average duration of active phase of labour in primigravida 186.3 minutes (3hr 6min) and 140.76 minutes (2 hour 20 minutes) in multigravidae DH and 254.2min (4 hour 14 minutes) and 172.82 (2 hour 52 minutes) in VB groups seen in a study done by Palii SB et al.¹⁶ In primigravida the mean duration of active phase of first stage of labor was 156.7 min and 110.7min in valethamate group and injection drotaverine group respectively. The p value = 0.001 was highly significant. In multigravidae the mean duration of active phase of first stage of labor was 126.3 min and 96.2 min in valethamate group and injection drotaverine group respectively. The p value = 0.001 was highly significant in study of Changede PR.¹⁷ Sinhasane H et al concluded in their study that duration of active stage of labour was significantly less in drotaverine group (3 hr 50 min ± 159 and 2hr 29 min±61.5 in primigravida and multigravidae respectively) than valethamate group (4 hr 25 min±196.5 and 3hr21min±111.5 in primigravida and multigravidae respectively).¹⁸ Mishra et al found the rate of cervical

dilatation to be 2.05cm/hour in primigravida and 3.68cm/hour in multigravida given drotaverine compared to 1.53cm/hour in primigravida and 2cm/hour in multigravida given Valethamate. Similar results were found in studies done by Rohwer C et al, Palii SB et al, Sinhasane et al, Sharma JB et al, Devinder et al and Kolhon P et al including the present study, where rate of cervical dilatation in drotaverine group for primigravida and multigravida were 3.0 cm/hr and 3.5 cm/hr respectively compared to 2.67 cm/hr and 2.90 cm/hr in Valethamate group and the difference is statistically significant $p = <0.0001$ for both groups.^{14,16,148-21} Six studies (n = 820) described that administration of antispasmodics significantly increased the rate of cervical dilatation by an average of 0.61 cm/hour (MD 0.61 cm/hour; 95% CI 0.34 to 0.88).¹⁴ According to Palii SB et al cervical dilatation was 1.92cm/hr and 2.58cm/hr in primigravida and multigravidae respectively in DH group and 1.44 cm/hr and 2.19 cm/hr in VB group.¹⁶ Cervical dilatation was 3.8 cm and 2.68 cm in primi in DH and VB group and 4, 36 cm and 3, 3 cm in multi in DH and VB in a study done by Chagede et al.¹⁷ Cervical dilatation were 1.83cm±1.18 and 2.82cm±1.24 in primigravida and multigravidae in drotaverine group and 1.58cm±1.05 and 2.08cm±1.26 in primigravida and multigravidae in valethamate group.¹⁸ Dilatation in primiparous drotaverine group was 2.3±0.6 cm/hr in multigravidae 2.7±0.5 cm/hr respectively (Efficacy of intramuscular Drotaverine use for cervical dilatation in first stage of labour.²¹ Injection to delivery interval was 209.80 ± 45.13 min and 190.92 ± 38.96 min in valethamate and drotaverine group respectively. There is significant difference when two study groups were compared.

There is a strong correlation between cervical dilatation and no. of injection in a reciprocal manner (Pearson correlation coefficient; -1). Inj to delivery interval were 192.56 min± 75.479 and 249.13cm±88.321 in drotaverine and valethamate group respectively.¹⁵ In study of Sharma JB mean injection to delivery interval was 220.07±86.12 min and 194±57.04 min respectively.¹⁹ Mean injection to delivery interval were 183.2 min (SD 78.8) in the Drotaverine group compared to 206.5 min (SD 69.7) in the Valethamate group in study done by Madhu C et al.²² Maternal complications were comparable in both Drotavarine and Valethamate groups. Studies done by Devinder et al, Khosla et al, Tiwari et al and Sharma et al showed no major side effects with drotaverine and Valethamate bromide.^{20,23,24,19} Transient maternal tachycardia was noted in 16% of cases receiving Valethamate bromide in studies done by Khosla et al and Tewari et al, 28% of cases developed transient maternal tachycardia in study done by Devinder et al.^{23,24,20} Transient side effects such as foeto-maternal tachycardia, flushing of the face and dryness of mouth were noted with Valethamate. A few patients complained of headache in the Drotaverine group.²² Sinhasane et al had reported dryness of mouth, palpitation and transient fetal tachycardia were more among VB group in his study.¹⁸ Dryness of mouth, flushing of face and tachycardia were

more among VB group in another study.¹⁷ Total 17(4.72%) patients had atonic PPH. Out of them 7 was in Valethamate, 10 in drotaverine. In study by J.B Sharma, there was 18% incidence of PPH in drotaverine group.¹⁹ In another study had shown that total 14(4.7%) patients had atonic PPH. Out of them 5 were in Valethamate, 5 in Drotaverine.¹⁵ Out of 360 patients, 90.56% had spontaneous vaginal delivery, 1.39% had instrumental delivery and 8.05% had LSCS. There is no significant difference between the two groups. Similar results were found in studies done by Gupta et al and Dahal P et al.^{25,15} There was no significant difference in neonatal outcome in two groups. About 1.1% newborn suffered from suspected neonatal sepsis (2 in DH group versus 2 in VB group), 0.56% had meconium aspiration syndrome and 0.83% had birth asphyxia. They required NICU admission. There was also no statistical difference noted in the APGAR scores at 1 and 5 mins.⁷ Dahal P et al reported comparable fetal outcome in DH and VB group.¹⁵ Apgar score was comparable in both DH and VB seen in results of Palii SB et al.¹⁶

CONCLUSION

Although both Drotaverine hydrochloride and Valethamate bromide are safe for both mother and foetus Drotaverine is more effective than Valethamate bromide in reducing the duration of labour. It has definitely proven to shorten the duration of labour and provide early relief from distress for the labouring women. Thus, we can conclude that drotaverine hydrochloride has promising beneficial effects on labour and safe to use.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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