

Comparative Study of Drotaverine Hydrochloride and Valethamate Bromide in rate of cervical dilatation

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ABSTRACT

OBJECTIVE:

To evaluate and compare the effects of drotaverine and valethamate on cervical dilatation.

METHODS:

This was a prospective study conducted in a tertiary center over a span of 6 months. 90 patients were randomly allotted in 3 groups.

1. 30 patients (15 primigravida and 15 multigravida)- control group
2. 30 patients (15 primigravida and 15 multigravida) – Injection Drotaverine
3. 30 patients (15 primigravida and 15 multigravida) – Injection Valethamate

The drotaverine (D) and valethamate (V) groups were given intravenously 40 mg drotaverine hydrochloride to group D with every 2 hours for a maximum of 3 doses 8 mg valethamate bromide to group V with maximum of 3 doses one hour apart. The control group given 2ml inj. normal saline intravenously as placebo.

RESULTS:

In primigravidae and multigravidae the average duration of active phase is shortened by 3 hours with 2.9+1cm/ hour cervical dilatation in drotaverine group and 1 hour 45 minutes with 1.9+1.1cm/hour in valethamate group (p-value <0.05). There was no significant difference in the duration of second and third stages in both groups. No obstetrical complications or major side effects observed in both groups.

CONCLUSION:

Drotaverine accelerates labor better than of valethamae. The reduction of pain during labor is better with drotaverine when compared with valethamate.

KEY WORDS : Drotaverine, Velathamate, labor, cervical dilatation

INTRODUCTION:

In the era of 4G network and digitalization , every one wants delivery in the shortest possible time without compromising the maternal and fetous safety is beneficial for both obstetritian and the laboring woman. Labor is a multifactorial process involving good myometrial contractions, cervical ripening, dilatation and expulsion of the fetus and the placenta in an orderly manner. Various drugs are available to curtail the duration of labor e.g.: hyoscine – N- butylbromide, drotaverine and valethamate bromide. There has been an upsurge in use of these cervical dilators to avoid the complications of prolonged labor. along with early amniotomy and early administration of oxytocin, to accelerate labor many advise the use of antispasmodic agents like drotaverine, hyoscine butylbromide, dicyclomine valethamide bromide, etc. to hasten the first stage of labor.(18)

AIMS AND OBJECTIVE

1. To compare the duration of active 1st stage of labour in control group , group D and group V.
2. To compare pain

METHODS:

This was a prospective study conducted in a tertiary center over a span of 6 months. 90 patients were randomly allotted in 3 groups.

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Criteria for inclusion in study

1. Period of gestation > 28 weeks
2. Primigravida and multigravida
3. Spontaneous onset of labor
4. Patient in active phase of labor with well established uterine contractions and cervical dilatation 3 cm
5. Vertex presentation
6. Single live fetus
7. No cephalopelvic disproportion

Criteria for exclusion from study

1. Non cephalic presentation
2. Multiple pregnancy
3. Known hypersensitivity to Drotaverine or Valethamate bromide
4. Trial of labor

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

Group V (Velathamate group): Patient in this group were given injection Velathamate 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 30 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.

Time of injection: Injection drotaverine and velathamate was given to the mothers belonging to respected group after initial assessment. Progress of labor was assessed by per abdominal examination and per vaginal examination. The progress of labour was assessed by cervical dilatation, duration of first stage, duration of second and third stage and maternal side effects of drugs and complications if any noted. The data of the study was tabulated and statistical analysis was done and both drugs were compared for their efficacy, side effects along with control group.

RESULTS

TABLE 1:

DEMOGRAPHIC PROFILE				
DEMOGRAPHIC VARIABLE	GROUP D	GROUP V	GROUP C	P VALUE
AGE(years)	24.3 + 1.6	24.2+1.8	24.4+1.5	>0.05
GESTATIONAL AGE(weeks)	38.2+1.1	38.3+1.1	38.2+1.1	>0.05
PRIMI GRAVIDA	15	15	15	
MULTI GRAVIDA	15	15	15	
INITIAL CERVICAL DILATATION(cm)	3.6+0.5	3.6+0.5	3.6+0.4	

It was observed that 97% patient were of age group between 19 to 30 years and 2% were in between 31 to 35 years in the whole study group. They are distributed in the three groups in the manner that average age in each group remains same and that factor would be statistically insignificant.

In all the three groups primi and multi gravida were divided equally. Gestational age wise distribution shows that maximum 92 % patient were 37 to 40 weeks in all groups. And 8 % patients had 41 to 42 weeks gestation period.

TABLE 2:

LABOUR DURATION				
	GROUP D	GROUP V	GROUP C	P VALUE
TOTAL DURATION OF LABOUR (MIN)	187.8+49.6	220+52.3	321.9+56.4	>0.05
DURATION OF 1 ST STAGE(MIN)	145.3+19.7	179.6+24.2	289.7+36.3	>0.05
DURATION OF 2 ND STAGE(MIN)	28.9+10.2	29.4+10.4	30.4+10.9	>0.05
DURATION OF 3RD STAGE(MIN)	9.1+2.1	9.6+2.3	8.9+19	>0.05
RATE OF CERVICAL DILATATION(CM/HR)	2.9+1.0	1.9+1.1	1.7+0.5	<0.05

In group D 16 patient received only 1 injection, 9 patient received 2 injection and 5 patient received 3 injections. In the group V ,7 patient received 1 injections, 14 patient received 2 injections and 9 patient received 3 injections. It was seen that mean rate of cervical dilatation was 1.7 cm/hr in the control group,1.9 cm/hr in the velathamate group and in the drotaverine group rate of cervical dilatation was 2.9 cm/hr.

It is evident from the table that the difference in the rate of dilatation is significant. The mean duration of active phase of 1st Stage of labour was more in control group(289.7+36.3) followed by was Valethamate (179.6+24.2) and Drotaverine group (145.3+19.7). Mean duration of 2nd stage of labour was 30.4,29.4,28.9 minutes in control, Valethamate and Drotaverine group. 3rd stage had mean duration almost same in all the three groups.

TABLE 3:

Mode of delivery	No. of patients		
	GROUP D(N=30)	GROUP V(N=30)	GROUP C(N=30)
NORMAL	27(90%)	26(86.67%)	27(90.5%)
INSTRUMENTAL	1(3.33%)	2(6.67%)	2(6.67%)
LSCS	2(6.67%)	2(6.67%)	1(3.33%)

TABLE 4:

	No. of patients		
	Group D (N=30)	Group v (N=30)	Group v (N=30)
Side effects			
MATERNAL TACHYCARDIA	1	0	0
FETAL TACHYCARDIA	1	1	0
NAUSEA/VOMITING	2	1	0
FLUSHING	3	0	0
FETAL DISTRESS	3	2	2
PROLONGED 2 ND STAGE OF LABOUR	1	1	1
VAGINAL TEAR	1	1	1

Among velathamate group 86.67% patient were delivered by full term normal delivery with

Episiotomy while 6.67% delivered by forceps. It was found that out of those patients in Drotaverine group 90% delivered by full term Normal delivery with episiotomy and 1% by forceps delivery. In control group 8% had cervical tear. In valethamate group 28% had tachycardia, 8% had headache and 12% had dryness of mouth. While in Drotaverine group 12% had tachycardia and 6% had headache.

DISCUSSION

The mean age in control group was of 24.4+1.5 years while 24.2+1.8 and 24.3+1.6 years of those in Valethamate and Drotaverine group respectively. In a study conducted by Tripti N and Jyoti J (2009)²⁰ 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)¹⁹ mean age in valethamate group was 23.3 years and in Drotaverine group was 22.8years. Gestational age wise distribution shows that Maximum i.e. 92% patients were 37 to 40 weeks of gestation in control group and Drotaverine group respectively. Only 8% patients had 41 to 42 weeks gestation period in control group and Drotaverine group. The findings were consistent with the findings reported by Tripti N and Jyoti J(2009)²⁰ and Thapa M, *et al*¹⁹. Overall the rate of cervical dilatation in control group was 1.7cm/hr, in Valethamate group was 1.9cm/hr and in Drotaverine group was 2.9 cm/hr. Sharma JB, *et al*(2001)¹⁷ and Mishra SL, *et al* (2002)¹² also observed similar rate of cervical dilation in Valethamate Drotaverine group in their study. However

Tripti N and Jyoti J(2009)²⁰ 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. Which was comparable with the present study Mean duration of second stage in Valethamate group was 27.4minutes, in Drotaverine group was 28 minutes and in control group was 30.4 minutes. It is comparable with the study done by Tripti N and Jyoti J(2009)²⁰ there was no significant difference in second stage of labor. In another study by Madhu C, *etal*(2009)²² also, there was no significant difference in second stage of labor. There was no significant reduction in the duration of third stage of labor in Valethamate group and Drotaverine group as compared to control group. In study done by Tripti N and Jyoti J (2009)¹⁸ and another study by Madhu C, *et al* (2009)¹¹ there was no significant difference in third stage of labor. In control group 8% mothers had cervical tear. In valethamate group 28% had tachycardia, 8% had headache and 12% had dryness of mouth. While in Drotaverine group 12% had tachycardia and 6% had headache. Tripti N and Jyoti J(2009)²⁰ observed adverse effects like tachycardia and dryness of mouth which was more commonly associated with valethamate group compared to drotaverine group. In study by Madhu C, *et al* (2010)¹¹ noted transient side effects of tachycardia, flushing of face and dryness of mouth in valethamate group. In drotaverine group headache was noted. The outcome of delivery was similar in all the three groups. And no statistical significant difference was observed. Tripti N and Jyoti J (2009)²⁰ also reported no significant difference in neonatal outcome. In this study, we found that Drotaverine effect on shortening duration of labour was significantly better than Valethamate bromide with lesser side effects.

CONCLUSION

Thus from the above results and discussion 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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