Research Article

# Comparative study of Drotaverine Hydrochloride and Valethamide Bromide in progress of labour

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## Abstract

**Introduction:** Relieving pain and shortening the duration of labour has been the constant aim of obstetricians all over the world. Attempts have been made to shorten the labour and to ease the pain. Methods that aim at minimizing the incidence of functional cervical dystocia and cutting short the first stage of labour are welcomed both by the obstetrician and the patient. **Aims and Objectives:** To study the effect and efficacy of Drotaverine Hydrochloride and Valethamide Bromide in Progression of labour. **Material and Methods:** In the present study total 150 pregnant women were enrolled in the study and were divided in three groups. Group I (Valethamate bromide group), Group II (Drotaverine group) and Group III (Control group) containing 50 pregnant women each. Injection drotaverine or valethamate according to the study group to which they belonged 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. **Results:** All the three groups were comparable with respect to age, gravid status and gestational age. mean rate of cervical dilatation was 1.5 cm/hr, 1.9 cm/hr and 2.6 cm/hr in control, Valethamate and Drotaverine group patients. The mean duration of active phase of 1st Stage of labour was more in control group (305.6 ±53.88) followed by was Valethamate (158.78±58.9) and Drotaverine group (113.2± 60.8). The duatrtion 1st and 2nd stage of labour was significantly reduced in drotaverine group as compared to control and Valethamate group. The outcome of delivery was similar in both the groups. In control group 8% had cervical tear. While in Drotaverine group 12% had tachycardia and 6% had headache. **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.

**Keywords:** Drotaverine, Valethamate, cervical dilatation, active management of labour.

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## INTRODUCTION

Relieving pain and shortening the duration of labour has been the constant aim of obstetricians all over the world. Attempts have been made to shorten the labour and to ease the pain. Methods that aim at minimizing the incidence of functional cervical dystocia and cutting short the first stage of labour are welcomed both by the obstetrician and the patient.[1] Friedman EA (1956)[2] by a graphico-statistical analysis showed that duration of different stages of labour has individual variations. The mean duration of I and II stages in primigravida were 13.3 hours and 0.95 hours respectively. Multigravida has a short labour, a mean of about 7.7 hours for the stage I and 0.29 hours for the stage II. When the total duration of first and second stage of labor exceeds 18 hours (arbitary limit) it is defined as prolonged labor.[3] In prolonged labour, mother is exposed to a higher risk of infection, dehydration, ketosis, unrecognized obstructed labor. The

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fetus on the other hand is exposed to dangers of infection, asphyxia and excessive cranial moulding. So attempts to shorten the duration of labor without jeopardising maternal or fetal interests would seem warranted.[4,5,6] Thus various methods to hasten cervical dilatation are being used such as mechanical methods and Pharmacological methods. The mechanical methods[7-10] includes sweeping and stretching, hygroscopic dilators, amniotomy and putting rubber catheter. A pharmacological method [11-17] includes use of various drugs such as Relaxin, Oestradiol, Efosin, Hyalase, Buscopan, Oxytocin, Prostaglandins, Epidosin, Drotaverine hydrochloride. Now a days Valethamate bromide (Epidosin) and Drotaverine hydrochloride are being used most commonly. Thus the present study was conducted to study the effect of Drotaverine Hydrochloride and Valethamide Bromide in Progression of labour.

## AIMS AND OBJECTIVES

To study the effect and efficacy of Drotaverine Hydrochloride and Valethamide Bromide in Progression of labour.

## MATERIAL AND METHODS

The present study was carried out at ACPM Medical College and hospital, Dhule from January 2010 to October 2011 in the department of obstetrics and gynecology. For the purpose of study total 150 pregnant women fulfilling following inclusion and exclusion criteria were enrolled in the study.

### 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 3 groups.

**Group I (Valethamate bromide group):** Patients in this group were given injection Valethamate 8mg (1 ml) intramuscularly 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 II (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 III (Control group):** This group included 50 patients and no drug was given. Details of the study 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:** after assigning groups to the patients, they were given injection drotaverine or valethamate according to the study group to which they belonged. 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:** Antenatal characteristics of patients in control Valethamate and Drotaverine group

| Variable | | Control Group | Valethamate Group | Drotaverine Group |
|---|---|---|---|---|
| Age | 18-30 | 47(94%) | 47(94%) | 45(90%) |
| | 31-35 | 3(6%) | 3(6%) | 3(6%) |
| | >35 | 00 | 00 | 2(4%) |
| Gravid | Primigravida | 22(44%) | 20(40%) | 19(38%) |
| | Multi-Gravida | 28(56%) | 30(60%) | 31(62%) |
| Gestational age | 37 - 40 | 46(92%) | 50(100%) | 46(92%) |
| | 41 to 42 | 4(8%) | 00 | 4(8%) |

It was observed that 94% (47) patients were of age group between 18 to 30 years and 6% (3) were in between 31 to 35 years in the control and Valethamate group. It was found that 90% (45) patients in Drotaverine group belonged to age group between 18 to 30 years and 6% (3) were in between 31 to 35 years while only 4 %(2) was above 35 years. The mean age in control group was of 25.80±2.99 years while 25.18±4.08 and 24.26± 3.78 years of those in Valethamate and Drotaverine group respectively. Gravida wise distribution revealed that 44% patients were primigravida and 56% multigravida in control group while in Valethamate group 40% were Primigravida and 60% were multigravida In Drotaverine group 38% were primigravida and 62% were multigravida. 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. In Valethamate group all i.e. 100% patients were 37 to 40 weeks of gestation.

**Table 2:** Distribution according to Number of injection given and rate of cervical dilatation

| Variable | | Control Group | Valethamate Group | Drotaverine Group |
|---|---|---|---|---|
| No of Injections | 1 | NA | 6(12%) | 31(62%) |
| | 2 | NA | 15(30%) | 15(30%) |
| | 3 | NA | 29(58%) | 4(8%) |
| Rate of Cervical Dilatation (cm/hr) | | 1.5±0.5 | 1.9±0.7 | 2.6±0.5 |

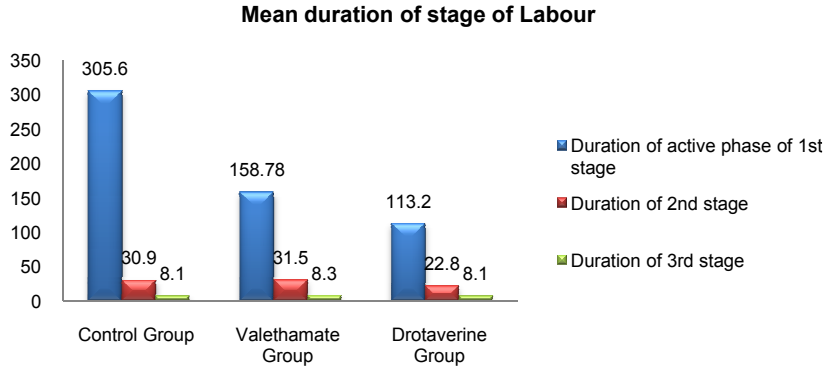
NA: not applicable

Intervention by Valethamate in the study group it was found that only 12% received only 1 injection while 30% had 2 injections and 58% receiving 3 injections. While It was found that 62% received only 1 injection of Drotaverine and 30% had 2 injections. Only 8% needed 3 injections. It was seen that mean rate of cervical dilatation was 1.5 cm/hr, 1.9 cm/hr and 2.6 cm/hr in control, Valethamate and Drotaverine group patients.

**Table 3:** Mean duration of stage of Labour in patients within control, Valethamate and Drotaverine group

| Stages of Labour | Control Group (mean± S.D) | Valethamate Group (mean± S.D) | Drotaverine Group (mean± S.D) |
|---|---|---|---|
| Duration of active phase of 1st stage (mins.) | 305.6 ±53.88 | 158.78±58.9* | 113.2± 60.8#$ |
| Duration of 2nd stage (mins.) | 30.9±7.6 | 31.5±12.5 | 22.8±9.4#$ |
| Duration of 3rd stage (mins.) | 8.1±2.2 | 8.3±2.2 | 8.1±2.2 |

*: Statistically significant difference between control and Valethamate Group.
#: Statistically significant difference between control and Drotaverine Group.
$: Statistically significant difference between Valethamate and Drotaverine Group.




It was evident from the table that mean duration of active phase of 1st Stage of labour was more in control group (305.6 ±53.88) followed by was Valethamate (158.78±58.9) and Drotaverine group (113.2± 60.8). Mean duration of 2nd stage of labour was 30.9±7.6, 31.5±12.5 and 22.8±9.4 minutes in control, Valethamate and Drotaverine group. 3rd stage had mean duration almost same all the three groups.

**Table 4:** Mode of delivery and maternal complication in control, Valethamate and Drotaverine group

| Variable | | Control Group | Valethamate Group | Drotaverine Group |
|---|---|---|---|---|
| Mode of delivery | Forceps | 4(8%) | 4(8%) | 2(4%) |
| | FTND | 1(2%) | 1(2%) | 6(12%) |
| | FTND+ E | 45(90%) | 45(90%) | 42(84%) |
| Maternal complication | Cervical tear | 4(8%) | 0 | 0 |
| | Tachycardia | 0 | 14(28%) | 6(12%) |
| | Headache | 0 | 4(8%) | 3(6%) |
| | Dryness of mouth | 0 | 6(12%) | 0 |

In control and Valethamate receiving group 90% patients were delivered by full term normal delivery with episiotomy while only 2% by only full term normal delivery while 8% delivered by forceps. It was found that out of those patients in Drotaverine group 84% delivered by full term Normal delivery with episiotomy and 12% by only full term normal delivery and 4% 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 25.80±2.99 years while 25.18±4.08 and 24.26± 3.78 years of those in Valethamate and Drotaverine group respectively. In a study conducted by Tripti N and Jyoti J (2009)[18] 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 22.8 years. In the present study in Valethamate group primigravida were 40% and multigravida were 60%.In Drotaverine group primigravida was 38% and multigravida was 62%.In control group primigravida was 44% and multigravida was 56%. Similar findings were also observed by Tripti N and Jyoti J(2009)[18] in their study. 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. In Valethamate group all i.e. 100% patients were 37 to 40 weeks of gestation. The findings were consistent with the findings reported by Tripti N and Jyoti J(2009)[18] and Thapa M, *et al*[19]. Overall the rate of cervical dilatation in control group was 1.5 cm/hr, in Valethamate group was 1.9 cm/hr and in Drotaverine group was 2.6 cm/hr. Sharma JB, *et al*(2001)[20] and Mishra SL, *et al* (2002)[21] also observed similar rate of cervical dilation in Valethamate Drotaverine group in their study. However Tripti N and Jyoti J(2009)[18] 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. Injection to delivery interval in Valthemate group was 191.3 minutes and in Drotaverine group was 137.1 minutes. Thus the delivery inreval was much reduced in Drotaverine group as compared to Valthemate group. similar findings were also reported by Tripti N and Jyoti J(2009)[18] and Sharma JB, *et al*(2001)[20]. Duration of active phase of 1st stage in Valethamate group was 158.78 mins, in Drotaverine group it was 113.2 minsand in control group it was 305.6 mins. Tripti N and Jyoti J(2009)[18] observe that the duration of active phase of 1st stage in Valethamate group was 177.4 minutes and in Drotaverine group was 113.5 minutes. Which was comparable with the present study. Mean duration of second stage in Valethamate group was 31.5 minutes, in Drotaverine group was 22.8 minutes and in control group was 30.9 minutes. The duration of second stage of labour was significantly reduced in Drotaverine group as compared to control and Valethamate group. However in study done by Tripati N and Jyoti J(2009)[18] there was no significant difference in second stage of labor. In another study by Madhu C, *et al*(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)[22] 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)[18] 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)[22] 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)[18] 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.

Drotaverine is associated with higher cervical dilatation, shorter 1st stage duration and less adverse effect.

## 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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