# Efficacy of intramuscular Drotaverine use for cervical dilatation in first stage of labour

Prabhneet Kalhon<sup>1</sup>, Alka B Patil<sup>2\*</sup>, Richa Patel<sup>3</sup>

Email: alkabpatil@rediffmail.com

#### Abstract

**Introduction:** Cervical dilatation is the resultant of all driving forces of uterine contractions acting against passive tissue resistance. Sometimes despite good uterine contractions and descent of presenting part, cervix fails to dilate or dilates very slowly. The condition is grouped as "Functional cervical dystocia". It is due to over activity of circular smooth muscles of the cervix. Considering various complications arising out of prolonged labour, various attempts have been made to accelerate labour and thereby shorten the duration of labour. This led to the concept of active management of labour. Aims and objectives: To study the efficacy of intramuscular Drotaverine used for cervical dilatation in first stage of labour. Material and methods: In the present study total 100 pregnant women were enrolled in the study and were divided in two groups. Group A (Drotaverine group) and Group B (Control group) containing 50 pregnant women each. Injection drotaverine was given to the mothers belonging to drotaverine 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. Results: Both the groups were comparable with respect to age, gravid status and gestational age. The mean rate cervical dilatation in primiparous women in control and Drotaverine group was 1.3±0.3 and 2.3±0.6 cm/hr respectively. In multi gravid mothers the mean rate of cervical dilatation in control and Drotaverine group was 1.6±0.6 and 2.7±0.5 cm/hr respectively. The duatrtion 1<sup>st</sup> and 2<sup>nd</sup> stage of labour was significantly reduced in drotaverine group as compared to control 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: It is concluded from the above said study that Drotaverine is a safe, potent and effective drug to shorten the first stage of labour.

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

# \*Address for Correspondence:

Dr. Alka B Patil, Professor and HOD, Department of OBGY, ACPM Medical College, Dhule, Maharashtra, INDIA.

Email: alkabpatil@rediffmail.com

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#### INTRODUCTION

Labour is a multifactorial process involving cervical ripening, myometrial contractions and dilatation resulting in expulsion of foetus and placenta in an orderly manner. Painless and short labour is desired by every mother and is a constant aim of obstetricians. The main emphasis was

on relief of pain. The problem of reduction of duration of labour was not given due consideration. During labour, the upper uterine segment contracts and is an active part. whereas the lower uterine segment dilates and is a passive part. The progress of labor is assessed by progressive dilatation of cervix and the descent of the presenting part. In Prolonged labour, mother is exposed to higher risk of infection, dehydration and ketosis. Foetus is exposed to higher risk of infection, asphyxia and excessive cranial moulding. Considering these facts, many attempts have been made to accelerate labour and thereby to shorten the duration of labour without ieopardizing fetal and maternal interest.<sup>2</sup> There are many causative factors associated with prolonged labour such as initial state of cervix, rate of cervical dilatation, intensity of uterine contractions, presentation and cephalopelvic disproportion. Friedman EA (1956)<sup>3</sup> by a graphico-statistical analysis showed that duration of different stages of labour has individual

<sup>&</sup>lt;sup>1</sup>Consultant Gynaecologist, Civil Block Hospital, Sector 22, Chandigarh, INDIA.

<sup>&</sup>lt;sup>2</sup>Professor and HOD, <sup>3</sup>Resident, Department of OBGY, ACPM Medical College, Dhule, Maharashtra, INDIA.

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. Cervical dilatation is the resultant of all driving forces of uterine contractions acting against passive tissue resistance. Sometimes despite good uterine contractions and descent of presenting part, cervix fails to dilate or dilates very slowly. The condition is grouped as "Functional cervical dystocia". It is due to over activity of circular smooth muscles of the cervix. Considering various complications arising out of prolonged labour. various attempts have been made to accelerate labour and thereby shorten the duration of labour. This led to the concept of active management of labour. The various methods used to hasten cervical dilatation are mechanical methods and Pharmacological methods. The mechanical methods<sup>4-7</sup> includes sweeping and stretching, hygroscopic dilators, amniotomy and putting rubber catheter. A pharmacological method<sup>8-14</sup> includes use of various drugs such as Relaxin, Oestradiol, Efosin, Hyalase, Buscopan, Prostaglandins, Epidosin, Oxytocin, Drotaverine hydrochloride. Now a days Valethamate bromide (Epidosin) and Drotaverine hydrochloride are being used most commonly. In the present study we tried to study the efficacy of Drotaverine hydrochloride in Progression of labour.

# AIMS AND OBJECTIVES

To study the efficacy of intramuscular Drotaverine used for cervical dilatation in first stage 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 100 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 2 groups.

**Group A (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 B (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: injection drotaverine was given to the mothers belonging to drotaverine 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: Antenatal characteristics of patients in control and Drotaverine group

Variable	Control Group (mean± S.D)	Drotaverine Group (mean± S.D)	Significance
Age (years)	25.80±2.99	24.26± 3.78	Not significant
Gestation Age(wks)	39.08±1.03	38.3±0.9	Not significant
Primigravida	22(44%)	19(38%)	Not significant
Multi-Gravida	28(56%)	31(62%)	Not significant

It was observed that mean age in control group was of  $25.80\pm2.99$  years while  $24.26\pm3.78$  years of those in

Drotaverine group. Mean gestation age of patients was 39.08±1.03 and 38.3±0.9 weeks in control and

Drotaverine group. Gravida wise distribution revealed that 44% patients were primigravida and 56%

multigravida in control group while in Drotaverine group 38% were primigravida and 62% were multigravida.

Table 2: Mean rate of cervical dilatation according to gravidity

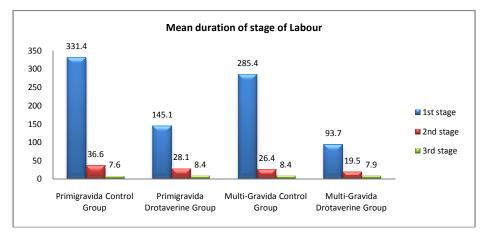
Gravida	Control Group Cms/hr	Drotaverine Group Cms/hr	Significance
Primigravida	1.3±0.3	2.3±0.6	Significant
Multi-Gravida	1.6±0.6	2.7±0.5	Significant

It was evident from the table that the mean rate cervical dilatation in primiparous women in control and Drotaverine group was 1.3±0.3 and 2.3±0.6 cm/hr

respectively. In multi gravid mothers the mean rate of cervical dilatation in control and Drotaverine group was 1.6±0.6 and 2.7±0.5 cm/hr respectively.

Table 3: Mean duration of stage of Labour according to gravidity

Gravida	Stage of lobour	Control Group (mean±S.D) mins	Drotaverine Group (mean±S.D) mins	Significance
	First stage	331.4± 42.4	145.1±58.5	Significant
Primigravida	Second stage	36.6±3.4	28.1±9.9	Significant
	Third stage	7.6±2.1	8.4±2.2	Not Significant
	First stage	285.4 ± 53.8	93.7±54.2	Significant
Multi-Gravida	Second stage	26.4±6.9	19.5±7.6	Significant
	Third stage	8.4±2.3	7.9±2.2	Not Significant



In pramigravida mothers mean duration of  $1^{st}$  stage of labour was  $331.4\pm42.4$  and  $145.1\pm58.5$ minutes in control and Drotaverine group. Mean duration of  $2^{nd}$  stage of labour was  $36.6\pm3.4$  and  $28.1\pm9.9$  minutes in control and Drotaverine group. In multigravida mothers the duration

of  $1^{st}$  stage of labour was much less  $(93.7\pm54.2)$  in Drotaverine group as compared to control group. The duatrtion  $1^{st}$  and  $2^{nd}$  stage of labour was significantly reduced in drotaverine group as compared to control group.

Table 4: Mode of delivery in patients of control and Drotaverine group

Mode of delivery	<b>Control Group</b>	<b>Drotaverine Group</b>
Forceps	4(8%)	2(4%)
FTND	1(2%)	6(12%)
FTND+ E	45(90%)	42(84%)
Total	50(100%)	50(100%)

In control 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.

 Table 5: Maternal complication in control and Drotaverine group

Maternal complications	<b>Control Group</b>	<b>Drotaverine Group</b>
Cervical tear	4(8%)	0

Tachycardia	0	6(12%)
Headache	0	3(6%)
Dryness of mouth	0	0
Absent	46	41

In control group 8% had cervical tear. 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 24.26± 3.78 years of those in Drotaverine group. In a study conducted by Tripti N and Jyoti J<sup>15</sup> mean age in Drotaverine group mean age was 22.76 while in another study by Thapa M, et al<sup>16</sup> mean age in Drotaverine group was 22.8 years. Mean gestation age of patients was 39.08±1.03 and 38.3±0.9 weeks in control and The findings were consistent Drotaverine group. with the findings reported by Tripti N and Jyoti J<sup>15</sup> and Thapa M, et  $al^{16}$ . In Drotaverine group primigravida were 38% and multigravidas were 62%. In control group primigravida were 44% and multigravidas were 56%. Tripti N and Jyoti J<sup>15</sup> observed 60% and 40% mothers were primigravida and multigravida respectively in Drotaverine group which was comparable with the present study. The rate of cervical dilation in Primigravida of control group was 1.3 cm/hr whereas that of of drotaverine group was 2.3 cm/hr. The rate of cervical dilation in Multigravida of control group was 1.6 cm/hr whereas that of Drotaverine group it was 2.7 cm/hr. Sharma JB, et al<sup>17</sup> and Mishra SL, et al<sup>18</sup> also observed similar rate of cervical dilation in primigravida and multigravida group in their study. Whereas in study done by Tripti N and Jyoti J<sup>15</sup> rate of cervical dilatation in primigravida of Drotaverine group was 2.89 cm/hr. In multigravida rate of cervical dilatation was 4.55 cm/hr in Drotaverine group which was higher as compared to the present study. In pramigravida mothers mean duration of stage of labour was  $331.4 \pm$ 42.4 145.1±58.5minutes in control and Drotaverine group. Whereas in multigravida mothers the duration of 1<sup>st</sup> stage of labour was much less (93.7±54.2) in Drotaverine group as compared to control group. The overall duration of active phase of 1st stage in Drotaverine group was 113.2 mins and in control group it was 305.6 mins. Thus the delivery interval was much reduced in Drotaverine group as compared to control group. Tripti N and Jyoti J<sup>15</sup> observe that the duration of active phase of 1st stage in Drotaverine group was 113.5 minutes which was similar to the present study. In pramigravida mothers the mean duration of 2<sup>nd</sup> stage of labour was 36.6±3.4 and 28.1±9.9 minutes in control and Drotaverine group whereas in multigravida mothers it was 26.4±6.9 and 19.5±7.6 minutes in control and Drotaverine group. The distortion 2<sup>nd</sup> stage of labour was significantly reduced in drotaverine group as compared to control group. Whereas

Tripati N and Jyoti J<sup>15</sup> and Madhu C et al<sup>19</sup> observed was no significant difference in second stage of labor in their study. There was no significant reduction in the duration of third stage of labor in Drotaverine group as compared to control group. In study done by Tripti N and Jyoti J<sup>15</sup> and another study by Madhu C et al<sup>19</sup> there was no significant difference in third stage of labor. In control group 8% mothers had cervical tear. While in Drotaverine group 12% had tachycardia and 6% had headache. Tripti N and Jyoti J<sup>15</sup> observed adverse effects like tachycardia and dryness of mouth. In study by Madhu C, et al<sup>19</sup> noted headache in drotaverine group. The outcome of delivery was similar in both the groups. And no statistical significant difference was observed. Tripti N and Jyoti J<sup>15</sup> also reported no significant difference in neonatal outcome. Thus we observed that effect of Drotaverine on shortening duration of labour was significantly better with lesser side effects. Drotaverine was associated with higher rate cervical dilatation, shorter 1<sup>st</sup> stage duration and less adverse effect.

### **CONCLUSION**

It is concluded from the above said study that Drotaverine is a safe, potent and effective drug to shorten the first stage of labour.

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