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Original Research Article

A comparative study on the efficacy of drotaverine and valethamate on cervical dilatation during labour: a prospective study from a tertiary care hospital of Rajasthan

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ABSTRACT

Background: Numerous drugs have been used to shorten the active phase of labour. how rationale is to use these drugs to shorten the active phase of labour? do they really shorten the duration of labour? What adverse effects do they have on the baby and the mother? These questions were the basis to perform the present study of comparing two of such drugs, injection drotaverine and injection valethamate bromide in primi and multigravidas.
Methods: A randomised control trial was conducted to compare the efficacy of drotaverine and valethamate on cervical dilatation during labour among 140 cases (70 cases each) in Department of Obstetrics and Gynaecology, RNT Medical College, Udaipur (Rajasthan).
Results. The mean duration of first stage of labor was 190.87±38.7 minutes in the Drotin group, 257±44.54 minutes in the epidosin group and 286.68±103.1 minutes in the control group. These differences were statistically significant. There was no significant difference in the duration of second and of third stage.
Conclusion: Baseline cervical dilatation and effacement were comparable in both the groups. The rate of cervical dilatation was significantly faster among drotin group than valethamate. Mean injection to delivery interval was also significantly shorter in valethamate group compared to Drotin group.

Keywords: Valethamate, Drotin, Drotaverine

INTRODUCTION

Although labour is a natural process, it has been proved by various studies that avoiding undue prolongation of labour by pharmacological means has a very important role to play in making it a safe and predictable event for both the mother and the obstetrician. Active intervention may be in the form of artificial rupture of membranes, oxytocin for augmentation of uterine contractions, analgesics for pain relief or antispasmodics for cervical dilatation.

The aim of active management is to reduce the total duration of labour without causing any adverse effects to the mother and fetus. All these causes increased physiological burden for the mother and these events may eventually cause complications in the 2nd stage and the puerperium. A short 1st stage of the labour is naturally of dual advantage, both to the obstetrician and the patient. The study aims to compare the efficacy and safety of drotaverine hydrochloride and valethamate bromide in accelerating labour, minimizing complications, and optimizing perinatal outcomes.[1]

The present study has been done to observe the effect of IV drotaverine on duration of the first stage of labor and to compare it with valethamate bromide in uncomplicated primi and 2nd gravidae.[2]

Aims and objectives

Aim and objectives were to evaluate the acceleration effect of Drotin and Epidosin on the dilatation of the cervix in both primigravidae and multigravida, to note the time interval between injection of (Drotin and Epidosin) and delivery and compare them and to determine deleterious side effects if any of the drugs affecting either mother or foetus.

METHODS

A comparative study on the efficacy of drotaverine and valethamate on cervical dilatation during labour will be conducted in the department of obstetrics and gynecology at Pannadhay Rajkiya Mahila Chikitsalya RNT medical college Udaipur (Rajasthan) from the May 2025 to July 2025.

Study design

The study was randomised control trial.

Study area

The department of obstetrics and gynaecology at Pannadhay Rajkiya Mahila Chikitsalya RNT medical college Udaipur (Rajasthan).

Study population

The study population will be selected from the patients admitted in antenatal ward of obstetrics and gynaecology department.

Sample size

Based on mean duration of 132.67±60.24 minutes in the epidosin group and 175.92±90.56 minutes (reference cited below) in drotaverine group and treatment effect of 43 at 90% power and α of 0.05% (2 sided) the calculated sample size is 70 in each group.

Stratification

The study population will be stratified into two groups- Group (I): primigravida and the group (II): multigravida.

Sampling

Randomisation will be done by the restricted block method.

Inclusion criteria

Patients with primi and multi gravida, age between 18-35 years, intact membrane with vertex presentation. Regular established uterine contraction at the rate of 2/10 minutes with each contraction lasting for 20 seconds. Cervical dilation 3-4 cm were included in the study.

Exclusion criteria

Patients with malpresentation, twin pregnancy, cervical surgery in past or history of cervical injury. Induced labor, maternal systolic pressure below 100 mmHg or above 150 mmHg. Known hypersensitivity to drotaverine or valethamate bromide. If any other spasmolytic agent had been used within the 24 hours were excluded from the study.

Ethical approval will be taken from Institution ethical committee, RNT medical college Udaipur (raj) before starting the study. Inform consent will be taken from all subjects willing to participate before enrolling them in the study. Finding from the study will not be revealed to any other person, it will be kept confidentiality.

Detail history of cases will be taken regarding age, occupation and socioeconomic status. Their presenting complaints will be recorded with special attention to period of amenorrhea, duration since onset of labour pain, leaking per vaginum and other complain. If any obstetric history elicited regarding outcome of previous pregnancies, any history of prolong labour, retained placenta, abortion, preterm labor or still birth. Past history regarding any major illness or systemic disease will also be taken.

Detail clinical and physical examination will be performed. Per abdomen examination with special attention for height of the uterus, presentation and frequency of contractions will be noted. Foetal well-being will be monitored by noting the heart rate, rhythm and regularity of foetal heart sound. By per vaginum examination cervical dilatation, effacement, consistency and station of presenting part will be noted. Pelvic examination will be performed to exclude any pelvic contraction or cephalopelvic disproportion.

Routine investigations advised including Hb, BT CT, blood grouping, blood sugar, sickling, VDRL, HIV, HbS-Ag and urine for routine and the microscopic examination.

After obtaining the homogenous group based on inclusion criteria, cases will be randomly assigned to group I-drotaverine and group II to valethamate bromide. The medicine will be injected in patients with established labour i.e. at 3 or 4 cm cervical dilatation with regular uterine contraction of >2 per 10 minutes and each lasting for 10 seconds.

In group I (n=70) cases received IV drotaverine 40 mg in supine position. Injection will be repeated after 2 hours as per requirement (Cervical dilatation <7 cm) to maximum of three injections.

In group II (n=70) cases received IV injection of valethamate bromide 8 mg at hourly interval to maximum of three.

Continues monitoring of maternal and fetal condition will be observed. Any abnormality if detected will be managed accordingly. Evaluation of uterine activity will be observed 1/2 hourly to assess the frequency and duration of contraction.

All events of labour will be graphically recorded in the form of partograph.

Outcome variables like injection delivery interval, total doses of drug required, route of delivery, incidence of operative interference, duration of first, second and third stages of labour, amount of blood loss, complications of the third stage like cervical tear, retained placenta, post-partum haemorrhage etc. will be noted.

Foetal outcome in terms of live or stillbirth, weight, Apgar scoring at 1 min and 5 min were recorded. Both mother and the baby were followed up for at least 24 hours.

RESULTS

Majority of distribution of respondents by gravida was contributed to primis 74.3% (Statistically insignificant).

Drotaverine hydrochloride increased the average cervical dilatation by 3.4cm in primigravidae, and valethamate bromide by 3.6cm compared to control group.

Drotaverine hydrochloride increased cervical dilatation by 3.7 cm in multiigravidae, and valethamate bromide by 3.5 cm compared to control group.

Drotaverine hydrochloride increased the average rate of cervical dilatation by 1.55 cm/hr in primigravidae, and valethamate bromide by 1.33 cm/hr compared to control group.

Drotaverine hydrochloride shortened the mean duration of active phase of labour in primigravidae by 202.32±34.7 minutes and valethamate bromide by 237±43.53 minutes compared to control group.

Drotaverine hydrochloride increased the average rate of cervical dilatation by 1.88 cm/hr in multigravidae and Valethamate bromide by 1.44 cm/hour compared to control group.

Drotaverine hydrochloride shortened the duration of active phase of labour in multigravidae by 190.87±38.7 minutes. and valethamate bromide by 257±44.54 minutes. compared to control.

There was no increase in instrumental delivery in either of the groups given drotaverine or valethamate. Indications for LSCS in control group were fetal distress and secondary arrest of cervical dilation. Indications for LSCS in drug groups was not pertaining to drug administration.

Table 1: Distribution of the respondents by gravida among Drotin and Epidosin group.

Gravida	Drotin group, N (%)	Epidosin group, N (%)	Total, N (%)	Chi- square test
Primigravida	48 (68.6)	56 (80.0)	104 (74.3)	Value=1.9, df=1, p=0.168
Multigravida	22 (31.4)	14 (20.0)	36 (25.7)	
Total	70 (100.0)	70 (100.0)	140 (100.0)	

Table 2: Distribution of the respondents by baseline cervical dilatation between Drotin and Epidosin group among primigravidae.

Baseline cervical condition in primigravidae	Drotin group, mean±SD	Epidosin group (in cm) mean±SD	T test
Cervical dilatation	3.4±0.8	3.6±0.4	Value=1.854, df=102, p=0.066
Cervical effacement	39.9±9.7	38.7±8.2	Value=-1.474, df=102, p=0.143

Table 3: Distribution of the respondents by baseline cervical dilatation between Drotin and Epidosin group among multigravida.

Baseline cervical condition in multigravidae	Droti group, mean±SD	Epidosin group (in cm), mean±SD	T test
Cervical dilatation	3.7±0.4	3.5±0.4	Value=1.462, df=34, p=0.152
Cervical effacement	42.9±12.5	41.78±14.2	Value=0.843, df=34, p=0.404

Table 4: Distribution of the respondents by various parameters of acceleration effect between Drotin and Epidosin group among primigravidas.

Acceleration effect (primigravidae)	Drotin group, mean±SD	Epidosin group (in cm) mean±SD	T test
Rate of cervical dilation (cm/hr)	1.55±0.46	1.33±0.23	Value=3.1506, df=102, p=0.0021
Duration of 1st stage (in minute)	202.32±34.7	237±43.53	Value=4.44, df=102, p=0.0001
Duration of 2nd stage (in minute)	18.02±4.84	20.21±3.19	Value=-2.759, df=102, p=0.0069
Duration of 3rd stage (in minute)	12.08±3.27	12.64±2.74	Value=-0.9503, df=102, p=0.344
Mean injection to delivery interval (in minute)	231.47±53.3	273.78±39.11	Value=-4.365, df=102, p=0.0001

Table 5: Distribution of the respondents by various parameters of acceleration effect between Drotin and Epidosin group among multigravida.

Acceleration effect (multigravidae)	Drotin group, mean±SD	Epidosin group (in cm), mean±SD	T test
Rate of cervical dilation (cm/hr)	1.88±0.44	1.44±0.10	Value=3.66, df=34, p=0.000
Duration of 1st stage (in minute)	190.87±38.7	257±44.54	Value=4.897, df=34, p=0.000
Duration of 2nd stage (in minute)	14.79±3.92	21.08±0.98	Value=-2.553, df=34, p=0.000
Duration of 3rd stage (in minute)	11.21±3.26	13.69±2.61	Value=-2.015, df=34, p=0.053
Mean injection to delivery interval (in minute)	204.77±53.2	294.11±26.58	Value=-4.766, df=34, p=0.000

Table 6: Distribution of the respondents by mode of delivery between Drotin and Epidosin.

Mode of delivery	Drotin group, N (%)	Epidosin group, N (%)	Total, N (%)	Chi-square test
NVD (±RMLE)	54 (77.2)	46 (65.7)	98 (70.0)	Value=4.64, df=2, p=0.098
Assisted	12 (17.1)	12 (17.1)	24 (17.1)	
LSCS	4 (5.7)	12 (17.1)	16 (11.4)	
Total	70 (100.0)	70 (100.0)	140 (100.0)	

Table 7: Distribution of the respondents by fetal complications between Drotin and Epidosin group.

Fetal complications	Drotin group, N (%)	Epidosin group, N (%)	Total, N (%)	Fisher exact test
Yes	2 (2.9)	12 (17.1)	14 (10.0)	Value=7.937, df=1, p=0.03
No	68 (97.1)	58 (82.9)	126 (90.0)	
Birth asphyxia	2 (2.9)	2 (2.9)	4 (2.9)	Value=0.0, df=1, p=0.380
Fetal bradycardia	0 (0.0)	4 (5.7)	4 (2.9)	Value=6.118, df=1, p=0.059
MAS with fetal bradycaedia	0 (0.0)	4 (5.7)	4 (2.9)	Value=6.118, df=1, p=0.059
NICU for LBW	0 (0.0)	2 (2.9)	2 (1.4)	Value=3.029, df=1, p=0.248
Total	70 (100.0)	70 (100.0)	140 (100)	

Drotaverine hydrochloride and valethamate bromide compared favourably with each other with respect to maternal and fetal outcomes.

DISCUSSION

Various perspective, randomized controlled clinical studies that compared drotaverine hydrochloride with placebo, and/or valethamate bromide have been carried

out. In the present study, drotaverine hydrochloride and valethamate bromide were given intravenously at 3-4cms cervical dilatation in 2 groups of demographically similar women with term pregnancy in active labour, and compared with a control group.[3] The concept of active management of labor gained strength in clinical practice with the availability of cervical smooth muscle dilators. Drotaverine and valethamate are more frequently used by many institutes of obstetrics and fetal medicine.

In our study we evaluated and compared the effect of DH and VB on cervical dilatation, duration of second and third stages of labor and third stage complications. After intravenous (IV) administration the drotaverine is rapidly absorbed and has half-life is 12 minutes, reaches maximum concentration in 45 minutes. The primary elimination half-life is 2.4 hours. It does not cross placental barrier and metabolized by liver. It is excreted through urine and feces as unchanged drug.[4,5] After intravenous (IV) of valethamate action starts with in 5 to 10 minutes. Its plasma half-life is 4 hours. It crosses the placental barrier and is also secreted in breast milk, but has no proven deleterious effects on fetus and baby. It is completely metabolized by liver and excreted in urine as both unchanged drug and metabolites.[6,7]

Both the drugs are easily available even in rural setup, less expensive, easy to administer, no need of anesthetist and easy to monitor with less side effects.

Our study found an increasing role of drotaverine hydrochloride in reducing the total duration of labor, hastening cervical dilatation, ensuring smooth progress of labor with good maternal and fetal outcome. It is concluded that overall efficacy of drotaverine was superior than the valethamate bromide.

The drugs drotaverine and valethamate are in the practice of clinical obstetrics. Both the drugs effectively relieve the maternal pain by reducing the cervical contractile response and shorten the duration of labor. Drotaverine is found to be better than valethamate in shortening the duration of labor and gives better pain relief. But both the drugs had no major side effects.

Outcome of labour

As both the Drotin and Epidosin reduce the duration of 1st stage less operative interferences was required in these two groups. in comparison to control group.

In present study 77.2% of Drotin group had spontaneous vaginal delivery. The 17.1% had forceps delivery for prolonged II stage and 5.7% (4 cases) was delivered by caesarean section for foetal distress. In Epidosin group 65.7% had spontaneous delivery, 17.1% (12 cases) was delivered by outlet forceps application for foetal distress, 11.4% patients had undergone LSCS for foetal distress. Hence it can be seen that the incidence of operative interference was least in Drotin group.

Cervical dilatation

In present series the average rate of cervical dilatation was 1.55 cm/ hr in primi Drotin group, thus it increases the rate of cervical dilatation by 0.46 cm/ hr in primigravidae and 1.88 cm/hr in multi Drotin group so it increases the rate of cervical dilatation by 0.44 cm/ hr in multigravida. In Epidosin group mean rate of cervical dilatation was 1.44 cm/hr in primiparas thus it increases the rate of cervical dilatation by 0.23 cm/ hr in primigravidae. Rate of cervical dilatation in multigravida was 1.44 cm/hr and it increased rate of cervical dilatation by 0.10 cm/hr.

The rate of cervical dilatation is 1.92 cm/hour and 2.58 cm/hour with drotaverine in primigravidae and multigravidae respectively whereas it is 1.44 cm/hour and 2.19 cm/hour with valethamate in primigravidae and multigravidae respectively. Both drotaverine and valethamate are effective in cervical dilatation but drotaverine is superior to valethamate. The data from the studies of Sharma et al, Mishra et al and Madhu et al also support these findings.[9,10,12]

Effect on I stage of labour

Present study shows duration of active phase to be 202.32±34.7 min in primigravida and 190.87±38.7 min in multigravida given drotaverine compared to 237±43.53min in primigravida and 257±44.54 min in multigravida given valethamate bromide. Rate of cervical dilatation was 1.55±0.46 and 1.88±0.44 cm/hour in group I and II respectively. They observed drotaverine hydrochloride to be a better drug for cervical dilatation than valethamate bromide.

The first stage of labor is longest and more painful especially in primigravidae. The smooth muscle content of cervix is 6 to 25% that offers contractile response to the advancing fetal head. This provides the physiological basis to use smooth muscle relaxants. The administration of smooth muscle relaxants at an appropriate time and dilatation phase can reduce the duration of labor successfully while providing pain reduction. Ever since Farkas et al concluded that drotaverine effectively relieves the cervical smooth muscle spasm, many obstetricians used drotaverine for accelerating labor and proved it as an effective cervical dilator.[8] Our study also proved the same. In the study done by Sharma et al with drotaverine and valethamate in acceleration of labor, he concluded that both are effective but drotaverine accelerated labor more rapidly with less side effects.[9] dilatation interval was significantly reduced with drotaverine 193.96 minutes (3 hours 13 minutes) in contrast to valethamate bromide group 220.68 minutes (3 hours 40 minutes).

In the study conducted by Mishra et al it was proved that drotaverine is highly effective cervical dilating agent compared to valethamate and control groups.[10]

The average duration of 3 cm to full cervical dilatation was

3 hours 25 minutes (205 minutes) in primigravidae and 1 hour 45 minutes (105 minutes) in multigravidae with drotin and 4 hours 35 minutes (275 minutes) in primigravidae and 3 hours 20 minutes (200 minutes) in multigravidae with epidosin. They concluded that both the drugs were effective but epidosin was better in multigravidae.

In the study conducted by Soni et al and Madhu et al they proved that both the drugs were effective in cervical dilatation but drotaverine hydrochloride is superior to valethamate bromide with less side effects.[11,12]

In the present study the mean duration of active phase was 186.3 minutes (3 hours 6 minutes) with drotaverine and 254.2 minutes (4 hours 14 minutes) with valethamate in primigravidae and 140.76 minutes (2 hours 20 minutes) with drotaverine and 172.82 minutes (2 hours 52 minutes) with valethamate in multigravida.

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 multigravida given drotaverine compared to 196 min in primigravida and 176.1 min in multigravida given valethamate bromide.[14]

Studies done by Devinder et al and Sharma et al showed no major side effects with drotaverine and valethamate bromide.[8,15]

Second stage of labour

In present study mean duration of second stage of labour in Drotin group was in 18.2±4.84 min primi patients, and 14.79±3.92 min in multi patients. In Epidosin group, mean duration of second stage of labour in primi patients was 20.21±3.19 min and in multi patients it was 21.08±0.98 min. This shows the drugs Drotin and Epidosin mainly affect the dilatation phase of labour.

Complications

Maternal complications

In the present study there is no significant difference in the duration of second and third stages with both the drugs and no increase in obstetrical complications. This is supported by the studies done by Sharma et al, Anju et al and Madhu et al.[9,12,13] Some obstetricians have reserved opinions that the cervical spasmolytic action of drotaverine could weaken the uterine contractions thus delaying the progress of labor. However, no scientific studies are available in defence of such opinions. But our study and previous studies proved that drotaverine hydrochloride had no such effect.

Neonatal complications

As Drotin does not cross the placental barrier it did not had any adverse effect on neonatal outcome. Neonatal complications were more or less same in all two groups except total 4 neonatal death due to birth asphyxia occurred in both group, 2.9% in Epidosin, and 2.9% in Drotin group. Incidence of fetal bradycardia was 5.7% only in epidosin group.

The APGAR scores were also not affected in both groups. Multigravida expressed definite satisfaction with pain experience compared to their previous labor pains. This is more with drotaverine than valethamate. This comparison is not obtained in primigravidae as they have no such experiences of labor pains previously.

The sum effect of reduction in total duration of labor reduced the maternal morbidity. The process of labor as such becomes less anxious and less painful experience fulfilling the aim of the obstetrician and desire of the patient.

Limitations

Limitations of this comparative study include the potential bias in the study design, such as randomization and blinding, which can affect the results validity. Additionally, the study may not account for all factors influencing cervical dilatation, such as matenal health, fetal position and other obstetric variables. The results should be interpreted with caution and consider in the context of the study's design and limitations.

CONCLUSION

A randomized control trial was conducted to compare the efficacy of drotaverine and valethamate on cervical dilatation during labour among 140 cases (70 cases each) in dept of obgy in RNT medical college Udaipur (Rajasthan).

Baseline cervical dilation and effacement were comparable in both the groups.

The rate of cervical dilatation was significantly faster among drotaverine group than valethamate. Mean injection to delivery interval was also significantly shorter in drotaverine compared to valethamate group.

Overall maternal complications were similar among two groups. fetal complications were significantly more among valethamate group compared to drotaverine group.

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