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ORIGINAL RESEARCH

A Hospital Based Prospective Study To Compare The Efficacy Of Drotaverine Hydrochloride And Valethamate Bromide On Cervical Dilation In Active Labour At Newly Established Tertiary Care Centre

[1]Gunvanti Meena, [2]Priyanka Joshi, [3]Ashish Prajapat

[1]Assistant Professor, [3]Medical Officer, Department of Obstetrics & Gynaecology, Government Medical College, Dungarpur, Rajasthan, India
[2]Assistant Professor, Department of Obstetrics & Gynaecology, Government Medical College, Bharatpur, Rajasthan, India

Correspondence:
Ashish Prajapat
Medical Officer, Department of Obstetrics & Gynaecology, Government Medical College, Dungarpur, Rajasthan, India
Email: ashishprajapati05@gmail.com

ABSTRACT

Background: Labour is a natural physiological phenomenon of childbirth. Painless and short labor is desired by every woman and is a constant aim for obstetrician. To avoid prolonged labour and its ill effects, sedation, amniotomy, oxytocin and prostaglandin have been used. The aim of this study to compare the efficacy of drotaverine hydrochloride and valethamate bromide on cervical dilation in active labour at newly established tertiary care centre.

Materials& Methods: This prospective study was conducted in Govt. Hospital for maternal & child health care at the Institute of Obstetrics and Gynaecology attached to Government Medical College, Dungarpur, Rajasthan, India during one year period. The patients were divided into 3 groups of 50 patients. Group I (Normal labour patients) (N=50), Group II (Patients who received Inj. Drotaverine Hydrochloride) (N=50) and Group III (Patients who received Inj. Valethamate Bromide) (N=50). Various parameters of duration of labor, mode of delivery, maternal and fetal complications and side effects of these drugs were compared in three groups.

Results: Drotaverine hydrochlomide and Valethamate bromide achieved 53% and 38% reduction in mean duration of active phase of labour respectively compared with control group. The mean rate of cervical dilatation was 2.66 cm/hrfaster with Drotaverine and 1.50 cm/hr with epidosin compared to control. The mean drug delivery interval was 47.72% shortened by Drotaverine and 35.90% shortened by Valethamate compared to Active phase Delivery interval of Controlgroup.

Conclusion: Drotaverine hydrochloride is a superior cervical dilatation agent significantly reducing the duration of labour without any ill effects on the motheror the fetus. It is significantly better than Valethamate bromide with less side effects due to selective action. Hence it is recommended that Drotaverine Hydrochloride may be given to low-risk women in active labour.

Keywords: Cervical Dilation, Drotaverine Hydrochloride, Valethamate Bromide, Active Labour.

INTRODUCTION

Labour is a natural physiological phenomenon of childbirth. It is amultifactorial spontaneous process which involves myometrial contractions,cervical ripening and dilatation, and expulsion of the fetus and placenta in anorderly manner.[1] In the process of labour, polarity of the uterus is maintained byactive contraction of upper uterine segment. The driving forces of uterinecontraction act upon the cervix which plays the role of innocent obstruction due topassive tissue resistance. It has been proved that cervical dilatation is one of theimportant factors which determine the duration of labour. The most common causeof prolonged first stage of labour is cervical spasm due to the overactivity of thecircular muscle fibres of cervix, which may be increased in presence ofinflammation injury or fibrosis of cervix or due to fear tension pain syndrome.[2]

Prolonged labour results in maternal exhaustion. At this crucial juncture, somemedication which overcomes the functional overactivity of the circular muscles of cervix, without giving rise to complications would help the patient and theobstetrician.The foetus is also exposed to complications like increased risk of infections, asphyxia and compression of cranial contents. To avoid prolonged labour and its ill effects, sedation, amniotomy, oxytocin and prostaglandin have been used. However, use of oxytocin and prostaglandins are not without serious side effects and these cannot be used safely by nursing officers who are to monitor labour cases in service hospitals.[3]

Drotaverine Hydrochloride: It is a phosphodiasterase 4 enzyme inhibitor a new addition to cervical dilator. It was initially used in Europe for spasmodic condition like renal, ureteric and biliary colic and in dysmenorrhea.[4,5]Its use for cervical dilatation was first studied by Chinoin in 1963 in Hungary.[6]

Valethamate Bromide (Epidosin): It is an ester of quatery ammonium compound; it is an anticholinergic, antispasmodic, musculotropic and neurotropic agent having peripheral action similar to atropine. It is a potent and rapidly acting drug which helps in cervical dilatation. It has side effect like dryness of mouth, flushing of face, nausea, Vomiting, nervousness, giddiness, hypotension due to its effect in smooth muscle of vessel wall.[6,7]AE Czeizel and M. Rockenbauer (1980-81)[8]first reported about theusefulness of Drotaverine Hydrochloride in threatened abortion and later, on itsusefulness in accelerating cervical dilatation in labour.Indeed, pharmacological manipulation of the cervix to produce dilatationwithout inducing myometrical activity would be similar to surgically removing theresistance of the cervix. The aim of this study to compare the efficacy of drotaverine hydrochloride and valethamate bromide on cervical dilation in active labour at newly established tertiary care centre.

MATERIALS& METHODS

This prospective study was conducted in Govt. Hospital for maternal & child health care at the Institute of Obstetrics and Gynaecology attached to Government Medical College, Dungarpur, Rajasthan, India during one year period. Primigravidae and multigravidae who fulfilled the inclusion & exclusion criteria were assigned Group I, Group II, Group III as they arrived, after obtaining an informed consent. The patients were divided into 3 groups of 50 patients. Group I (Normal labour patients) (N=50), Group II (Patients who received Inj. Drotaverine Hydrochloride) (N=50) and Group III (Patients who received Inj. Valethamate Bromide) (N=50).

INCLUSION CRITERIA

1. Term pregnancy in active labour – initial cervical dilation of 3–4 cms and cervical effacement 75%.
2. Vertex presentation
3. No cephalopelvic disproportion
4. No high risk factors
5. Labour was accelerated with syntocinon whenever needed.
6. All the patients were managed actively

EXCLUSION CRITERIA

1. Medical disorders complicating pregnancy
2. Obstetric complications within high risk category
3. Malpresentation
4. Women with previous caesarian section

METHODS

A detailed history regarding age, parity, socioeconomic status, occupation, booking, gestational age, H/o. any medical disorders or high-risk factors was elicited.

A thorough general examination was done followed by detailed obstetric examination to know the height of fundus, presentation and position of the fetus, fetal heart sounds with respect to rhythm, rate and intensity.

Vaginal examination was done in detail to know the position, effacement and dilation of cervix, position and station of presenting part, presence or absence of membranes, and for assessment of pelvis and cephalopelvic disproportion.

MANAGEMENT

All these patients were entered into partograms and the progress of labour,uterine contractions and the fetal heart rate were monitored carefully.

Patients were selected randomly and were allotted to 1 of following groups,regardless of age and parity.

- Group I - Control Group
- Group II - Received 1 ampoule of Drotaverine Hydrochloride 40 mgintravenously at 2 hourly intervals up to a maximum of 3 doses,starting at 3-4 cms cervical dilatation.

- Group III - Received, 1 ampoule of Valethamate bromide 8mg intravenously athourly intervals up to a maximum of 3 doses, starting at 3-4 cmscervical dilatation.

Per vaginal examination was carried out usually at an interval of 2 hoursand findings noted. Artificial rupture of membranes was done soon after administration of drug at 4 cm cervical dilatation, and duration of active phase offirst and second stages of labour recorded.

Standard parameters for maternal andfetal well being were monitored as specified by Dawn. If desired rate ofcontractions were not achieved oxytocin drip was started. Mode of delivery,maternal side effects and fetal outcomes were noted and tabulated. Appropriatenon-parametric tests, X^2 test and analysis of variants (ANOVA) were applied forassessment of statistical significance.

RESULTS

Our study showed that maximum no. of patients (73.33%) was 21 to 30 years of age group in all three groups (table 1).

Table 1: Characteristics of patients in three groups

Characteristics	Group I N = 50	Group II N = 50	Group III N = 50	Chi-square test	P-value
Age in years					
15 – 20	12	15	11	9.74	>0.05
21 – 25	25	28	29		
26-30	11	7	10		
31 – 35	2	0	0		
Parity					
Primigravida	25	25	25	0.872	1.00
Multigravida	25	25	25		

Drotaverine hydrochlomide and Valethamate bromide achieved 53% and 38% reduction in mean duration of active phase of labour respectively compared with control group. The mean rate of cervical dilatation was 2.66 cm/hr faster with Drotaverine and 1.50 cm/hr with epidosin compared to control. The mean drug delivery interval was 47.72% shortened by Drotaverine and3 5.90% shortened by Valethamate compared to Active phase Delivery interval of Control group (table 2).

Table 2: Test of significance

	Group I	Group II	Difference of means (mts)	Group III	Difference of means (mts)	Anova Test P value & significance
No.of Cases	50	50		50		
Mean Duration of Active Phase (minutes)	184.52 ± 71.38	86.96± 38.22	97.56	112.36 ± 44.34	70.16	F = 33.68 P<0.001*
Mean rate of	2.39 ±	5.05 ±	2.66	3.89 ±	1.50	F = 238.34

cervical dilatation (cm/hr)	1.03	2.12		1.70		P<0.001*
Mean Active phase / Drug – Delivery Interval (minutes	204.15 ± 75.58	106.72 ± 43.76	97.43	130.84 ± 44.20	73.31	F = 330.88 P<0.001*

Drotaverine hydrochloride and Valethamate Bromide compared favourably with each other with respect to maternal and fetal outcomes, except that Valethamate had a higher incidence of maternal side effect (table 3).

Table 3: Comparison Of Maternal And Fetal Outcomes

Outcomes		**Group I**	**Group II**	**Group III**
Mode	**Vaginal**	46	49	48
	Outlets Forceps	2	1	1
	LSCS	2	-	1
Cervical tears		-	2%	2%
Atonic PPH		-	-	-
Meconium-stained liquor		12%	8%	10%
Maternal Side Effects		4%	4%	8%
Apgar < 7/10 at 1 mt		2%	4%	4%
Apgar > 7 at 5 mt		100%	100%	100%

DISCUSSION

Acceleration of labor is considered to be an important factor in reducing maternal and neonatal morbidity.[1] Since long back Valethamate Bromide is used to relive cervical spasm.[7]

A newer drug Drotaverine is an iso-quinoline derivative acting by inhibition of phosphodiesterase enzyme type four that causes relaxation of smooth muscles. In addition it also has spasmolytic action.[6]

Drotaverine hydrochlomide and Valethamate bromide achieved 53% and 38% reduction in mean duration of active phase of labour respectively compared with control group, which is comparable to the study conducted by Devinderetal (2003)[9] (96.34±59.45minutes with Drotaverine and 128.78±58.99minutes with Valethamate). Randomised controlled clinical studies presented at the XVII FIGO World Congress held that the decrease in meanduration of Active phase with Drotaverine was 109 minutes compared with placebo, and 37.6 minutes compared with Valethamate.

The mean rate of cervical dilatation was 2.66 cm/hrfaster with Drotaverine and 1.50 cm/hr with epidosin compared to control, whichis comparable to the study by Devinderetal(2003)[9] (4.99±2.21cm/hr with Drotaverine and 3.74 ± 1.72 cm/hr with Valethamate). Goswami et al (2000)[10]noted that Drotaverine hastens cervical dilatation by 1.3 to 2.04 cm/hr compared tocontrol. Both Drotaverine hydrochloride and valethamate bromide had no effect onthe uterinecontractions.

In our study Drotaverine is used during active dilatory phase of labor and results were compared with IM Valethamate Bromide injection. It was found Intramuscular administration of Drotaverine significantly reduces the duration of cervical dilatation and total delivery time.

Drug is safe and does not alters delivery parameters, with no adverse effect on mother and fetus.[1,2,4,5]

Mishra SL et al (2002)[2] studied effect of Drotaverine and Valethamate Bromide on cervical dilatation. They found average rate of cervical dilatation in primigravida with Drotaverine was 2.05cm/hour and with Valethamate Bromide 1.53 cm/hour. In Multigravida it was 3.68 cm/hour and 2 cm/hour respectively. They found with Drotaverine the duration of labor was significantly shorten. In our study we have observed almost similar findings.

The mean first injection delivery internal with Drotaverine is 105.52±44.16minutes and 133.74±45.18minutes with Valethamate which is comparable to the study by Devinderetal[9] (129.82±63.75minutes with Drotaverine and 151.53±60.47minutes with Valethamate). The average duration of IIstage of labour was not affected by administration of drugs compared to control group.

94% cases in Drotaverine group required single injection, while 68% casesrequired single injection and 40% required 2 or more injections in Valethamategroup. The incidence of side effects was 4% with Drotaverine compared to 8%with Valethamate. Cervical tears were noted in 2%in both drug groups. No caseofatonicPPHwasnotedin all 3groups.

Regarding mode of delivery, in control group, 2 cases were delivered byoutlet forceps and 2 cases by LSCS. In Drotaverine group, only 1 case were deliveredby outlet forceps, and in Valethamate group 1 were delivered by outlet forceps and1 by LSCS. Thus, there was no increase in instrumental delivery in either of thedrug groups.

Regarding fetal outcome, thin meconium-stained liquor was noted in 12%,8% and 10% of cases in Group I, II and III respectively. All were NST reactive, delivered vaginally, and had Apgar > 7/10 at 5 minutes. There were nointrapartumor earlyneonatal deathsinall3 groups.

Drotaverine is associated with higher rate of cervical dilatation, shorten the first stage of labor with few adverse effects in therapeutic dose as compared to Valethamate Bromide.[11-14] In present study we also observed the Drotaverine group had identical results.

CONCLUSION

Drotaverine hydrochloride is a superior cervical dilatation agent significantly reducing the duration of labour without any ill effects on the motheror the fetus. It is significantly better than Valethamate bromide with less side effects due to selective action. Hence it is recommended that Drotaverine Hydrochloride may be given to low-risk women in active labour.

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