STUDY ON THE EFFECTIVENESS OF DRUGS USED FOR CERVICAL DILATATION TO REDUCE DURATION OF LABOUR AND FOETAL OUTCOME

Saroja Adapa[1], Sridevi Pottekula[2]

[1]Assistant Professor, Department of Obstetrics and Gynaecology, Osmania Medical College, Hyderabad.
[2]Assistant Professor, Department of Obstetrics and Gynaecology, Osmania Medical College, Hyderabad.

ABSTRACT

BACKGROUND

Normal labour is a difficult processes characterised by uterine action leading to cervical dilation and effacement followed by delivery of the foetus. Any procedure or drug, which decreases the duration of labour is a boon for both patient and obstetrician.

The aim of the study is to evaluate and compare the efficacy of drugs drotaverine and valethamate bromide in shortening the active phase of cervical dilations to decrease the duration of labour without affecting foetal outcome.

MATERIALS AND METHODS

This comparative study was done in the Department of OBG, Government Maternity Hospital (GMH), Sultan Bazar, Hyderabad, from January 2015 to June 2015 on 200 patients. The patients were randomly divided into two groups and drugs were given when cervix is 3-4 cm dilated and time duration till full dilation was noted. Group D- This group includes cases, which were given intravenous drotaverine 40 mg and repeated if necessary after two hours upto maximum of 3 injections. Group V- This group includes cases, which were given intravenous valethamate 8 mg every hour up to maximum of 6 injections. The patients and foetus were monitored by partogram.

RESULTS

In the present study, D-group injection dilatation interval in primigravida and second gravida was 210 minutes and 165 minutes respectively compared to V-group with 273 minutes and 203 minutes for primigravida and second gravida, respectively. The average cervical dilatation in primi and second gravida in D-group were 2 cm/hr. and 2.5 cm/hr. respectively and 1.5 cm/hr. and 2 cm/hr. in primi and second gravida in V-group, respectively. There is no significant difference in duration of second stage, third stage, side effects and Apgar score in both groups. Drotaverine is more effective than valethamate bromide.

CONCLUSION

Though both drugs can be used for shortening of active phase of labour, drotaverine is more effective. Both drugs have no side effects on the foetus.

KEYWORDS

Cervical Dilation, Labour, Active Phase.

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BACKGROUND

The phenomenon of labour is dynamic. From the onset of labour till delivery of the newborn, it is a myriad of changes including physical biochemical and hormonal activities that the human mind cannot decipher completely till today. It is essential to understand the physio-pharmacology of labour to manage this process more efficiently and potentially allows us to modify this process when required by the use of pharmacological agents to stimulate or inhibit labour. Cervical dilatations play an important role in the labour. The cervix is a fibromuscular organ composed of collagen, smooth muscles and glycosaminoglycans like dermatan sulphate and chondroitin sulphate. These glycosaminoglycans are negatively charged and hydrophobic and keeps the cervix firm. Cervix loses its firmness in pregnancy and in labour it loses its elasticity, viscosity and plasticity. During pregnancy and labour, the mature collagen with many crosslinks that are responsible for tensile strength are replaced by immature collagen with few crosslinks. The dermatan and chondroitin sulphates are replaced by hyaluronic acid, which is hydrophilic and it imbibes water and makes the cervix soft. In modern obstetrics, O'Driscoll et al found the concept of active management of labour. The aim of active management is to reduce total duration of labour without causing any adverse effect on the mother or foetus. Many times, it is observed that in spite of good uterine contractions, cervix fails to dilate or dilates very slowly. This functional cervical dystocia is probably due to over activity of smooth muscles present in the cervix. Smooth muscle relaxants decreases the incidence of functional cervical dystocia and cuts short the first stage of labour.

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Corresponding Author:
Dr. Saroja Adapa,
6-3-1216/4, Methodist Colony, Begumpet.
E-mail: dr.adapasaroja@gmail.com
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During labour, cervix undergoes two important changes effacement and dilatation. As stated by Friedman (1978) "except for cervical dilation and foetal descent, none of the clinical features of the parturient appear to be useful in assessing labour progression."

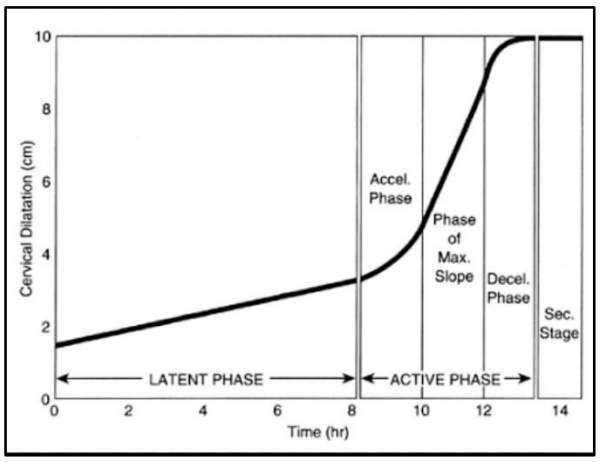

Figure 1. Friedman's Curve for First Stage of Labour

The pattern of cervical dilation during the course of normal labour takes the shape of a sigmoid curve. It can be divided into two phases-

1. Latent phase.
2. Active phase.

The active phase is further divided into three parts and they are-

1. Acceleration phase.
2. Phase of maximum slope.
3. Deceleration phase.

The duration of active phase has significant influence on the labour outcome.

Though many drugs are available to hasten cervical dilatation, drotaverine and valethamate are the most commonly used drugs. In this study, we compared efficacy and safety of these drugs.

Drotaverine- It is an isoquinolone derivative. It acts by inhibiting phosphodiesterase enzyme and increases cAMP, which dampens the contractions of smooth muscle cell by decreasing intercellular level of calcium. Drotaverine rapidly penetrates into organs after intravenous injections and does not cross placental barrier. The primary eliminations half-life after IV dosing is 2.4 hours. Except few side effects like nausea, constipation, hypotension and headache, it is safe in pregnancy.

Valethamate Bromide- It is an anticholinergic agent and should be stored in an airtight container. It is a competitive inhibitor of acetylcholine at the muscarinic receptors. Its plasma half-life is 4 hours. It crosses the placenta and secreted in breast milk. The side effects for this drug are tachycardia, dryness of mouth, flushing, headache, nausea and vomiting.

MATERIALS AND METHODS

This comparative study was done in the Department of OBG, GMH, Sultan Bazar, Hyderabad, from January 2015 to June 2015 on 200 patients including both primigravida and multigravida with gestational age between 38 weeks-41 weeks with their consent for study.

Inclusion Criteria- Primi and multi, age between 20-35 years, singleton pregnancy, gestational age 38 weeks to 41 weeks, cervical dilation of 3 to 4 cm and uterine contractions at the rate of 2-3 contractions with each lasting up to 20 seconds.

Exclusion Criteria- Twins, previous LSCS, malpresentations, CPD, foetal distress, hypersensitivity to either drotaverine or valethamate bromide, PIH.

After thorough history, clinical examination including pervaginal examination and basic investigations, they are randomly divided into 2 groups. 42 primigravidae and 58 multigravidae are included in the drotaverine group. 40 primigravidae and 60 multigravidae are included in the valethamate group.

Group D- This group includes cases, which were given intravenous drotaverine 40 mg and repeated if necessary after two hours upto maximum of 3 injections.

Group V- This group includes cases, which were given intravenous valethamate 8 mg every hour up to maximum of 6 injections.

In the study, patients with age between 20-35 years without obstetric complications, cervical dilation of 3-4 cm with good uterine contractions were included. They were monitored using partogram.

RESULTS

Comparison of different gravida in both groups.

Sl. No.	Gravida	Drotaverine	Valethamate
1.	Primigravida	42	40
2.	Second gravida	34	36
3.	Third gravida and more	24	24

Table 1. Comparison of Different Gravida in Both Groups

In this study, there are no significant difference in parity for both groups.

Gravida	<2 hours		2-4 hours		4-6 hours		6-8 hours	
	D %	V %	D %	V %	D %	V %	D %	V %
Primigravida	10	5	71	15	19	70	0	5
Second gravida	18	11	76	33	6	56	0	0
Third and more	33	25	67	75	0	0	0	0

Table 2. Comparison of Duration of Active Phase of Labour (1st Stage) with both Drugs

*D- drotaverine *V- valethamate.

Drotaverine is a better drug than valethamate for shortening of active phase.

Gravida	<1/2 hour		½-1 hour		1-2 hours	
	D%	V%	D%	V%	D%	V%
Primigravida	33	25	57	60	10	11
Second gravida	65	61	35	28	0	11
Third gravida and more	83	75	17	25	0	0

Table 3. Comparison of Second Stage of Labour in Both Groups

*D- Drotaverine; *V- Valethamate.

There is no significant difference in total duration of second stage of labour in both groups.

Gravida	0-10 Minutes		10-20 Minutes	
	D%	V%	D%	V%
Primi gravida	90	80	10	20
Second gravida	04	04	6	6
Third and more	92	92	0	8

Table 4. Comparison of Third Stage of Labour in Both Groups

*D- Drotaverine *V- Valethamate.

There is no significant difference in duration of third stage of labour in both groups.

Gravida		Apgar	Score	
	8-10		<6	
	D%	V%	D%	V%
Primigravida	90	87	10	13
Second gravida	100	100	-	-
Third gravid and more	100	100	-	-

Table 5. Comparison of Apgar Score in Both Groups

*D- Drotaverine; *V- Valethamate.

According to the data, both the drugs does not affect the Apgar score in the foetus.

DISCUSSION

In modern obstetrics, O'Driscoll et al found the concept of active management of labour. The aim of active management is reduction in the total duration of labour without adverse effects on mother and foetus. Assurance is given to every woman that her delivery is over within 12 hours.[1] The drugs drotaverine and valethamate bromide by hastening cervical dilatation play important role in active management of labour described by O'Driscoll et al. Drotaverine is an antispasmodic drug structurally related to papaverine. Drotaverine is a selective inhibitor of PDE IV inhibitor and has no anticholinergic effect.[2]

Parameter	Group	Anju Huria K. Indu Bala (December 2003)	S.L. Mishra Anju Toshniwal (2002)	J.B. Sharma (2001)	Present Study
Mean duration of injection dilatation interval	D - Group	Primi - 208.18 +89.44 mts.	Primi - 205 mts.	D - 193.96 mts.	Primi - 210 mts.
		Multi - 112.05 + 49.81 mts.	Multi - 105 mts.		Multi -165 mts.
	V - Group	Primi - 145.94 + 62.08 mts.	Primi - 275 mts.	V - 220.68 mts.	Primi - 273 mts.
		Multi - 104.37 + 45.23 mts.	Multi - 210 mts.		Multi - 203 mts.
Rate of cervical dilatation	D - Group	2.04 cm/hr.	Primi - 2.05 cm/hr.	D - 2.04 cm/hour	Primi - 2 cm/hr.
			Multi - 3.68 cm/hr.		Multi - 2.5 cm/hr.
	V - Group	2.71 cm/hr.	Primi - 1.5 cm/hr.	V -1.86 cm/hour	Primi - 1.5 cm/hr.
			Multi - 2 cm/hr.		Multi - 2 cm/hr.
Number of injections dilation	D - Group	Maximum 3 inj.	Primi - 2.1		Primi - 1.75
			Multi -1.3		Multi - 1.37
	V - Group	Maximum 4 inj.	Primi - 4.15		Primi - 4.5
			Multi - 3.16		Multi - 3.38
Duration of second stage and third stage		No difference	No difference	No difference	No difference
Side effects	D - Group	Nil	2%	Nil	Nil
	V - Group	+	8%	+	12%
Apgar		Not effected	Not effected	Not effected	No significant difference

Table 6. Comparison of Parameters in Different Studies

In the comparative study by Sharma JB and Pundir P et al, Maulana Azad Medical College, New Delhi, the injection to dilatation interval was significantly reduced in drotaverine group 193.96 minutes in contrast to valethamate group 220.68 minutes. The rate of cervical dilatation was 2.04 cm in drotaverine and 1.8 cm/hr. in valethamate group. Drotaverine accelerates labour more rapidly and with less side effects.[3]

Similar to Mishra SL, Anju Toshnival study, in my study also drotaverine is highly effective cervical dilating agent as compared to valethamate.[4]

In the present study, drotaverine group injection dilatation interval in primigravida and second gravida was 210 minutes and 165 minutes respectively compared to valethamate with 273 minutes and 203 minutes for primi and second gravidae, respectively (P value <0.05, which is statistically significant). In third gravidae, the difference was not significant. The average cervical dilatation in primi and second gravidae in drotaverine group were 2 cm/hr. and 2.5 cm/hr. respectively and 1.5 cm/hr. and 2 cm/hr. in primi and second gravidae in valethamate group, respectively (P value <0.05, which is statistically significant). In third gravidae, the difference was not significant. Only three cases in each group had caesarean section for foetal distress. Singh KC observed that shortening of first stage of labour was 28% if drotaverine was given when cervical dilation was 4 cm.[5]

Though in many studies, valethamate is reported to cause foetal tachycardia, but in my study, both drugs do not cause foetal distress and outcome is same.[6] There was no significant difference in duration of second stage, third stage of labour just like Madhu et al.[7] There is no difference in side effects and Apgar score in both groups. Drotaverine is more effective than valethamate bromide and scored over its rival in having absolutely no side effects. Though both drugs are effective, drotaverine is more effective in reducing duration of active phase.[8]

CONCLUSION

Though both drugs causes shortening of active phase, but drotaverine was more effective with minimum side effects and maximum foetal safety.

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