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A COMPARATIVE STUDY OF VALETHAMATE BROMIDE AND DROTAVERINE HYDROCHLORIDEON CERVICAL DILATATION IN ACTIVE LABOUR AT A TERTIARY CARE HOSPITAL

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ABSTRACT

Labour can be defined as the natural and physiological event of delivery of the child. It has been proved that the dilatation of cervix is one of the important factors determining the duration of labour. The prolonged labour will result in maternal exhaustion. In this crucial situation, certain drugs which will overcome the functional over activity of the circular muscles of cervix. The aim of the present study is to compare the effect of drugs - Drotaverine Hydrochloride and Valethamate Bromide in Shortening the duration of active phase of labour.

Among the patients in the study group, most of the subjects involved were of active fertile age group. The rate of cervical dilatation in active phase was more in group II and least in group I. Mean duration of II-stage of labour was found to be more in group-I followed by group III and II. Active phase first injection delivery interval was more in group I and least in group II. The character of amniotic fluid was mostly clear in all the three groups. Mode of delivery was normal vaginal delivery mostly in all the three groups. While observation of relation between drugs and fetal outcome, APGAR score was >7/10 in all the three groups at 1 minute and 5 minutes after delivery. Mean duration of active phase, Mean rate of cervical dilatation & Mean active phase are significant among the three groups.

Drotaverine hydrochloride is a superior cervical dilatation agent drug which significantly reduces the duration of labour with minimal ill effects on the mother and the fetus. It is significantly better than Valethamate bromide with minimal unwanted side effects due to its selective action.

KEY WORDS: Valethamate Bromide, Drotaverine Hydrochloride, Cervical Dilatation, Active Labour.

INTRODUCTION

Labour can be defined as the natural and physiological event of delivery of the child. It is a set of spontaneous and multi factorial events which involves coordination of myometrial contractions, cervical ripening and dilatation, with expulsion of the fetus and placenta in a controlled and orderly manner[1]. During the process of labour, the polarity of uterus is maintained by the active contraction of upper segment of uterus. The driving forces which causes uterine contractions also act upon the cervix which plays the major role of

innocent obstruction due to passive tissue resistance. It has been proved that the dilatation of cervix is one of the important factors determining the duration of labour[2].

It has been observed that sometimes though the contractions of uterus are sufficient, the cervix fails to dilate or dilates very slowly or partially[3]. The commonest cause of this prolonged first stage of labour can be cervical spasm due to the over activity of the circular muscle fibres of the cervix, which may be increased in the presence of inflammatory injury or fibrosis of the cervix or may be due to fear tension pain syndrome[4]. This prolonged labour will result in maternal exhaustion. In this crucial situation, certain drugs which will overcome the functional over activity of the circular muscles of cervix, without any events of complications would help the patient and also the obstetrician.

In 1963, at National Maternity Hospital, Dublin the active management of labour was introduced into clinical practice[5]. It's aim was to achieve reduced maternal and fetal distress along with shortening the duration of labour and anticipation and management of the complications[6]. To the principle of active management of labour, cervical smooth muscle relaxants are well accepted addendum. The present study was done to compare the efficacy of Valethamate bromide with Drotaverine hydrochloride on cervical dilatation in active labour and both study and control group.

MATERIALS AND METHODS

The aim of the present study is to compare the effect of drugs - Drotaverine Hydrochloride and Valethamate Bromide inShortening the duration of active phase of labour. The present study was conducted at Department of Obstetrics & Gynecology, Ayaan Institute of Medical Sciences, Kanakamamidi, Rangareddy dist, Telangana from February 2021 to February 2022.Ethical Clearance has been obtained from the Instituitional Ethical Committee. The subjects for the study are selected from the patients coming to OPD as per the inclusion and exclusion criteria. Term pregnancy in active labour – initial cervical dilation of 3 to 4 cms and cervical effacement 75%; Vertex presentation; No cephalopelvic disproportion; No high risk factors are the included in the study after obtaining informed consent. Exclusion criteria are Medical disorders complicating pregnancy; Obstetric complications within high risk category; Malpresentation; Women with previous caesarian section.

All the patients were divided into 3 groups of 100 each depending upon the drug being administered.

Group	Control/Study	Management	No. of Patients
Group – I	Control Group	Normal Labour	100
Group – II	Study Group	Received Inj.Drotaverine Hydrochloride	100
Group – III	Study Group	Received Inj.Valethamate Bromide	100

Primary data about age, parity, socioeconomic status, occupation,gestational age, any medical disorders or high risk factors were collected. A thorough general examination followed by detailed obstetric examination has been conducted to know the height of fund us, presentation and position of the fetus, fetal heart sounds with respect to rhythm, rate and intensity. Vaginal examination was also performed 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[7-9].

All the details were entered into partograms. The progress of labour, uterine contractions and the fetal heart rate were monitored carefully. Group II patients received 1 ampoule of Inj.Drotaverine Hydrochloride 40 mg intravenously 2ndhourly intervals up to a

maximum of 3 doses, starting at 3-4 cms cervical dilatation. Group III patients received, 1 ampoule of Inj. 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 at an interval of 2nd hourlyand findings are noted. Artificial rupture of membranes was done soon after administration of drug at 4 cm cervical dilatation, and duration of active phase of first and second stages of labour recorded. Standard parameters for maternal and fetal well being were monitored[10]. If desired rate of contractions were not achieved oxytocin drip was started. Mode of delivery, maternal side effects and fetal outcomes were noted and tabulated. Appropriate non-parametric tests, $\chi 2$ test and analysis of variants (ANOVA) were applied for assessment of statistical significance.

RESULTS

Among the patients in the study group, age group of 21 to 25 years were about 49% and 21 to 30 years age group were around 71.3%. so, most of the subjects involved were of active fertile age group as shown in Table 1.

Age in years	Group I N = 100	Group I N = 100	Group I N = 100	Percentage
15-20	20	28	25	24.3%
21-25	45	52	50	49%
26-30	26	19	22	22.3%
31-35	09	01	03	4.4%

Table 1: Distribution of cases according to age

Group	No. of Cases	Mean Duration (Minutes)	Difference of Means (Minutes)	Difference in Percentage
I	100	198.6		
II	100	86.4	112.2	56.5%
III	100	105.4	93.2	47%

Table 2: Duration of active phase of labour

Upon analysis of duration of active phase of labour, the difference of means between group-I & II was 111.2 min where as between group I & III was found to be 93.2 min as in Table 2.

Group	No. of Cases	Average rate of cervical dilatation (cm/hr)	Difference of Means (cm/hr)
I	100	2.01	
II	100	4.62	2.61
III	100	3.24	1.23

Table 3: Rate of cervical dilatation in active phase

From Table 3, we can observe that the rate of cervical dilatation in active phase was more in group II and least in group I.

Group	No. of Cases	Mean duration	Difference of

		(Minutes)	Means (Minutes)
I	100	20.40	
II	100	18.24	1.16
III	100	19.44	0.96

Table 4: Duration of II-stage of labour

In Table 4, the mean duration of II-stage of labour was found to be more in group-I followed by group III and II.

Group	No. of Cases	Active phase first injection delivery interval (Minutes)	Difference of Means (Minutes)	Difference in Percentage
I	100	214.4		
II	100	118.4	96.0	44.8
III	100	184.6	29.8	13.9

Table 5: Active phase first injection delivery interval

From Table 5, we can find that active phase forst injection delivery interval was more in group I and least in group II.

Oxytocin	Group-I n=100	Group-II n=100	Group-III n=100
Used	48%	44%	42%
Un-used	41%	50%	49%

Table 6: Oxytocin augmentation

Type of liquor	Group-I n=100	Group-II n=100	Group-III n=100	Fetal outcome
Clear	78	89	88	Good
Thin Meconium	6	4	6	Good
Thick Meconium	3	1	4	Good

Table 7: character of amniotic fluid

From Table 7, we observed that the character of amniotic fluid was mostly clear in all the three groups.

Group	No. of Cases	Normal vaginal delivery	Forceps delivery	LSCS
I	100	93	4	3
II	100	97	2	1
III	100	96	2	2

Table 8: Mode of delivery

From Table 8, the observation was that the mode of delivery was normal vaginal delivery mostly in all the three groups.

Group	No. of Cases	APGAR Score			
		1 minute		5 minute	
		<7/10	>7/10	<7/10	>7/10
I	100	3	97	0	100
II	100	4	96	0	100
III	100	3	97	0	100

Table 9: Relation between drugs and fetal outcome

While observation of relation between drugs and fetal outcome, APGAR score was >7/10 in all the three groups at 1 minute and 5 minutes after delivery.

Complications	Inj.Drotaverine Group	Inj.Valethamate Group	Control
Cervical tears	2%	1.5%	-
Atomic PPH	-	-	-

Table 10: Third stage complications

There were minimal third stage complication as shown in Table 10 in all the three groups.

Group	No. of Cases	No. of Injections	
		1	≥2
II	100	92%	8%
III	100	68%	32%

Table 11: Comparison of number of injections given

Most of the patients received one injection in comparison to number of injections given in all the three groups as shown in Table 11.

Side effects	Group II	Dose of drug (in mg)	Group III	Dose of drug (in mg)
Dryness of mouth	2	80	4	16
Vomiting	2	80	1	24
Tachycardia	1	80	3	16

Table 12: Untoward maternal effects after Inj.Drotaverine & Inj.Valethamate

Upon analysis from Table 12, untoward maternal effects after receiving injection, very few patients have complained of the uneasiness such as dryness of mouth, vomiting, nausea, tachycardia.

	Group I	Group II	Difference of means (minutes)	%	Group III	Difference of means (minutes)	%	Anova Test P value & significance
No. of cases	100	100			100			
Mean Duration of Active	164.22 ± 65.14	81.14 ± 34.26	83.08	50%	105.26 ± 41.24	58.96	36%	F=33.28 P=0.001 Significance

Phase (minutes)								
Mean rate of cervical dilatation (cm/hr)	2.25 ± 1.08	6.02 ± 1.9	3.77		3.26 ± 1.22	1.01		F=227.14 P=0.001 Significance
Mean Active phase / Drug – Delivery Interval (minutes)	189.12 ± 68.18	102.11 ± 38.86	87.01	46%	124.18 ± 44.8	108.23	57%	F=325.46 P=0.001 Significant

Table 13: Tests of statistical significance

From Table 13, upon analysis of statistical significance it can be found that the Mean duration of active phase, Mean rate of cervical dilatation & Mean active phase are significant among the three groups.

Outcomes		Group I	Group II	Group III
Mode	Vaginal	93	97	96
	Outlets forceps	4	2	2
	LSCS	3	1	2
Cervical tears		-	2%	2%
Atonic PPH		-	-	-
Meconium stained liquor		11%	6%	9%
Maternal side effects		3%	5%	8%
APGAR <7/10 at 1 min		3%	4%	3%
APGAR >7/10 at 5 min		100%	100%	100%

Table 14: Comparison of maternal and fetal outcomes

DISCUSSION

In the present study, it was noted that the mean duration of active phase of labour in control, Group II and III are similar to the study conducted by others[11-15]. Randomised controlled clinical studies presented at the XVII FIGO World Congress held that the decrease in mean duration of Active phase with Drotaverine was 109 minutes compared with placebo, and 37.6 minutes compared with Valethamate. In the present study, the decrease is 112.2 minutes in Drotaverine group compared to control, and 93.2minutes compared with Valethamate.

The rate of cervical dilatation in Group I, Group IIand in Group III are comparable to other studies[11-18]noted that Drotaverine hastens cervical dilatation by 1.3 to 2.04 cm/hr compared to control. In the present study, cervical dilatation was 2.61cm/hr faster with Drotaverine compared to control and 1.23 cm/hr faster with Valethamate. Both Drotaverine hydrochloride and valethamate bromide are found to have no effect on the uterine contractions.

The mean first injection delivery interval with Drotaverine is 118.4 ±32.84 minutes and 184.6 ± 38 minutes with Valethamate which is comparableto the study by *Devinder et al*

(129.82 ± 63.75 minutes with Drotaverine and151.53 ± 60.47 minutes with Valethamate).The average duration of II stage of labour was not affected by administration of drugs compared to control group.92% cases in Drotaverine group required single injection, while 68% cases required single injection and 32% required 2 or more injections in Valethamate group. The incidence of side effects was 5% with Inj.Drotarverine compared to 8%with Inj.Valethamate. Cervical tears were noted in 2% in both drug groups. No case of atonic PPH was noted in all the 3 groups.

Regarding mode of delivery, in control group, 4 cases were delivered by outlet forceps and 3 cases by LSCS. In Drotaverine group, 2 cases were delivered by outlet forceps, and in Valethamate group 2 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 6%,4% and 6% of cases in Group I, II and III respectively. All were NST reactive, delivered vaginally, and had Apgar > 7/10 at 5 minutes. Thick meconium wasnoted in 3 cases in control group – 2 delivered by LSCS, 1 by outlet forceps and 1delivered vaginally. Thick meconium noted in 4 cases in Drotaverine group were delivered vaginally, and of the 3 cases of thick meconium in Valethamate group, 1was delivered by LSCS and 2 by outlet forceps. All cases of thick meconium in all3 groups were NST reactive and had Apgar > 7/10 at 5 minutes. There was no intrapartum or early neonatal deaths in all 3 groups.

Mean duration of active phase of labour in control group was 164.22 ±65.14 minutes. The duration of active phase is reduced by 83.08 minutes(50% reduction) in Drotaverine group which is statistically significant($p = 0.001$) compared with control and 24.12 minutes faster than Valethamate. There was significant difference in rate of Cervical dilatation between thecontrol and other 2 groups ($p = 0.001$) with Drotaverine achieving 2.61cm/hr faster dilatation and Valethamate achieving 1.23cm/hr faster dilatation compared to control. Both Drotaverine Hydrochloride and Valethamate had no effect on the uterine contractions.

The mean first injections to Delivery interval is significantly reduced in both groups given drugs 50% reductions with Drotaverine and 36%reduction with Valethamate compared to the Active phase delivery internalin Control ($p = 0.001$).There was no significant shortening of II stage of labour. There was no increase in incidence of instrumental delivery or abdominal delivery in either Drotaverine or Valethamate groups.

The incidence of cervical tears was 2% in both drug groups.No case of atonic PPH noted in all 3 groups. Incidence of maternal side effects with drotaverine (3%) is significantly less compared to Valethamate (8%).There was no significant increase in incidence of meconium stained liquor in the drug groups compared to control.All newborns in all 3 groups had Apgar score > 7 at 5 minutes. There was no intrapartum or early neonatal deaths in all the study groups.

CONCLUSION

Drotaverine hydrochloride is a superior cervical dilatation agent drug which significantly reduces the duration of labour with minimal ill effects on the mother and the fetus. It is significantly better than Valethamate bromide with minimal unwanted side effects due to its selective action. Hence it can be recommended to administer Inj.Drotaverine Hydrochloride to low risk women in active labour.

The promising beneficial effects of Drotaverine hydrochloride are available in obstetric practice and in this study, it has definitely proven to shorten the duration of labour and provide early relief from distress for the labouring woman.

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