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Original Article

“Comparison of Drotaverine and Valethamate Bromide In First Stage Of Labor”

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ABSTRACT

AIM: To compare the efficacy and side effects of drotaverine and valethamate bromide in first stage of labor. **METHOD:** This study is a randomized prospective study done in JSS Hospital, Mysore, consisting of 200 pregnant women, 100 of whom were given drotaverine and 100, valethamate bromide when they entered active phase of labor, i.e., when cervix was 3-4 cm dilated and uterine contractions were effective. Drotaverine 40 mg was given IM 2nd hourly to a maximum of 3 doses and valethamate bromide was given half hourly to a maximum of 3 doses. **RESULTS:** The rate of cervical dilatation was more in the drotaverine group (3.31 cm/hr in primigravida and 3.71 cm/hr in multigravida) compared to valethamate group (2.58 cm/hr in primigravida and 2.61 cm/hr in multigravida). More number of women (72.9% of primigravida and 78.8% of multigravida) delivered within 2 hours in the drotaverine group compared to valethamate group. The difference was statistically significant. 72.9% of primigravida and 78.8% of multigravida required only 1 injection of drotaverine while 98.1% of primigravidas and 100% of multigravidas required 3 injections of epidisin. No significant maternal or fetal side effects were noted with both the drugs. **CONCLUSION:** Drotaverine is more effective than valethamate bromide in reducing the duration of active phase of labour. No major maternal or fetal side effects were noted in this study.

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1. Introduction

Prolonged labour had been a dreaded problem for the obstetrician. The most common cause of prolonged labour is cervical spasm due to over activity of circular muscle fibres of cervix, which may be increased in the presence of inflammation, injury or fibrosis of cervix or fear-tension-pain syndrome.¹

Application of antispasmodics in obstetrics to relieve cervical spasm was first introduced by Von Kries and his pupils in 1923. Today, with the advent of various forms of pharmacological interventions which have helped in shortening the duration of labour by augmenting uterine contractions or by accelerating the rate of cervical dilatation, the nightmare of prolonged labour and its consequences is rare.²

Drotaverine is an isoquinoline derivative which binds to the surface of smooth muscles and changes their membrane potential

and permeability. It inhibits phosphodiesterase IV enzyme which breaks cAMP and cGMP which play an important role in regulation of smooth muscle tone.³ It acts specifically on spastic sites and corrects the cAMP and calcium imbalance relieving smooth muscle spasm.⁴

Valethamate bromide or epidisin is from the group of 'Efosin' described by Steinmann (1954) for use in hastening labour.⁵ It is an ester with quaternary N atom, which by virtue of its anticholinergic, parasympatholytic and musculotropic action relieves spasm of smooth muscle of cervix. These two drugs are used for cervical dilatation in modern obstetrics without deleterious effects on mother/ fetus.³

In this era where the focus is shifting from 'wait and watch' policy to 'active intervention sooner than later' to ensure better labour outcomes, these drugs used in synergy with analgesics enable modern obstetricians to make labour and delivery a safe and pleasant experience for the mother.

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2. Materials And Methods

This study was conducted in JSS Hospital, Mysore. It is a randomized prospective study consisting of 200 pregnant women in established labor, i.e., those with effective uterine contractions and 3-4 cm cervical dilatation satisfying inclusion criteria, which are gestational age 37-41 weeks and cephalic presentation. Women with Previous uterine scar, malpresentation, cephalopelvic disproportion and multiple pregnancy were excluded from the study.

These women were allotted in two groups based on the table of random numbers from 1 to 200. Group A included 100 women to whom Inj. Drotaverine 40mg (2ml) was given IM at 3-4 cm cervical dilatation and repeated 2 hourly for a maximum of 3 doses. Group B included 100 women to whom Inj. Valethamate Bromide 8 mg (1ml) was given IM at 3-4 cm cervical dilatation and repeated ½ hourly to a maximum of 3 doses.

Partogram was recorded for all the patients entering the study.

The following parameters were recorded and analysed:

1. Gravidity
2. Duration of active phase of labour
3. Rate of cervical dilatation
4. Number of injections required
5. Side effects of drotaverine and valethamate bromide.
6. Complications in III stage of labor
7. Fetal complications

All data obtained was compiled and analyzed regarding comparative efficacy, safety and acceptability of the two drugs involved.

Following statistical methods were employed in the present study

- Ø Frequencies/ Descriptives
- Ø Contingency coefficient (Cross Tabs)
- Ø ANOVA-One way

3. RESULTS

In group A, 64 were primigravida and 36 were multigravida. In group B, 63 were primigravida and 36 were multigravida. The contingency coefficient revealed a non-significant association between drugs and parity.

Among the primigravida, 17 women, i.e., 26.2% underwent LSCS in group A and 9 women, i.e., 14.3% underwent LSCS in group B. Among the multigravida, 3 women, i.e., 8.3% underwent LSCS in each group. The contingency coefficients revealed a non-significant association between the incidence of LSCS and the groups.

Hence women who underwent LSCS were excluded from the study to avoid confusion while comparing various parameters of the study. After excluding patients who underwent LSCS, new groups were named. [Table 1]

More number of women (72.9% of primigravida and 78.8% of multigravida) delivered within 2 hours in the drotaverine group compared to valethamate group (44.4% of primigravida and 36.4% of multigravida). The contingency coefficient revealed a significant association between the groups and duration of active phase. [Table 2]

One way analysis of variance revealed significant difference between rates of cervical dilatation in various groups. The rate of cervical dilatation was more in the drotaverine group (3.31 cm/hr in primigravida and 3.71 cm/hr in multigravida) compared to valethamate group (2.58 cm/hr in primigravida and 2.61 cm/hr in multigravida). [Table 3]

72.9% of primigravida and 78.8% of multigravida required only 1 injection of drotaverine while 98.1% of primigravidas and 100% of multigravidas required 3 injections of valethamate bromide. The contingency coefficient revealed a highly significant association between the groups and number of injections required. [Table 4]

One multigravida given valethamate bromide developed cervical tear and one developed paraurethral tear. There was atonic PPH in one multigravida given drotaverine and retained placenta in one primigravida given drotaverine. No significant association was found between the groups and III stage complications.

No side effects were observed in multigravida given drotaverine and only 1 primigravida given drotaverine had side effect (vomiting). Both primigravida and multigravida given valethamate bromide experienced relatively more side-effects like vomiting (1 primigravida), cervical tear (1 multigravida), maternal tachycardia (1 primigravida and 1 multigravida) and fetal tachycardia (3 primigravida). But there was no significant association between the incidence of side effects and the groups. (CC = 0.278; P < .297).

No significant association was found between the incidence of fetal complications and the groups.

Table 1: Description of new groups

Group	Description	No. of women
AP	Primigravida given Drotaverine	48
BP	Primigravida given VB*	54
AM	Multigravida given Drotaverine	33
BM	Multigravida given VB*	33

*VB - Valethamate bromide

Table 2: Duration of active phase of labor

Group	Duration of active phase (hours)			Total
	<2	2-4	>4	
AP	35 (72.9%)	12 (25.0%)	01 (2.1%)	48 (100%)
BP	24 (44.4%)	26 (48.1%)	04 (7.4%)	54 (100%)
AM	26 (78.8%)	7 (21.2%)	-	33 (100%)
BM	12 (36.4%)	21 (63.6%)	-	33 (100%)
Total	97 (57.7%)	66 (39.3%)	5 (3%)	168 (100%)

CC=0.384; P<.000 (HS)

Table 3: Rate of cervical dilatation

Group	No.	Rate of cervical dilatation (cm/hr)		
		Mean	SD	Range
AP	48	3.31	1.07	1.33-6.00
BP	54	2.58	0.91	0.92-4.80
AM	33	3.71	1.60	1.50-9.00
BM	33	2.61	0.98	1.50-6.00
Total	168	3.10	1.18	0.92-9.00

F=9.813; P<.000 (HS)

Table 4: Number of injections required

Group	Rate of cervical dilatation (cm/hr)			Total	Mean
	1	2	3		
AP	35 (72.9%)	11 (22.9%)	2 (4.2%)	48 (100%)	1.31
BP	-	01 (1.9%)	53 (98.1%)	54 (100%)	2.98
AM	26 (78.8%)	06 (18.2%)	01 (3.0%)	33 (100%)	1.24
BM	-	-	33 (100%)	33 (100%)	3.00

CC=0.691; P<.000 (HS)

Table 5: Duration of active phase of labor in various studies

Study	Mean duration of active phase (minutes)			
	Primigravida		Multigravida	
	Drotin	VB*	Drotin	VB*
Malaysarkar et al., ⁶	174.7	196	148.2	176.1
SL Mishra et al., ⁴	205	275	105	210
Kamlesh Tewari et al., ¹	-	140.7	-	140.2
Kaur Devinder et al., ²	143.91	180.40	99.7	146.6
Present study	123.12	160.00	113.94	147.12

*VB - Valethamate bromide

Table 6: Rate of cervical dilatation in various studies

Study	Mean duration of active phase (minutes)			
	Primigravida		Multigravida	
	Drotin	VB*	Drotin	VB*
Sharma JB et al., ⁷	2.04	1.86	-	-
SL Mishra et al., ⁴	2.05	1.53	3.68	2.00
K. Tewari et al., ²	-	1.89	-	2.52
K. Devinder et al., ¹	3.18	2.41	4.45	2.97
Present study	3.31	2.58	3.71	2.61

*VB - Valethamate bromide

Discussion

Although labor is a natural process, it has been proved by various studies that avoiding undue prolongation of labor 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, oxytocics for augmentation of uterine contractions, analgesics for pain relief or antispasmodics for cervical dilatation.

Drotaverine and valethamate bromide are widely used now-a-days for cervical dilatation in active phase of labor. Various trials have been done comparing the safety and efficacy of the above two drugs.

In our study, there was a statistically significant reduction in the duration of active phase of labor in both primigravida and multigravida given drotaverine when compared with valethamate bromide. The results of another study done by Malaysarkar et al., [6] 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. SL Mishra et al., [4] also found duration of active phase of labor to be less in women given drotaverine (205 min in primigravida and 105 min in multigravida) compared to valethamate bromide (275 min in primigravida and 210 min in multigravida) [Table 5]

SL Mishra et al., [4] found the rate of cervical dilatation to be 2.05cm/hour in primigravida and 3.68cm/hour in multigravida given drotaverine compared to 1.53cm/hour in primigravida and 2cm/hour in multigravida given epidosisin. Similar results were found in studies done by Sharma JB et al., [7] and K Devinder et al., [1], including the present study. [Table 6]

Less number of injections were needed in patients given drotaverine when compared with epidosis in the previous studies. In the study done by SL Mishra et al.,[4], average number of injections required in women given drotaverine was 2.1 in primigravida and 1.3 in multigravida compared to 4.5 in primigravida and 3.16 in multigravida given valethamate bromide. The same is reflected in the present study also.

Side effects were very few in the present study, with 2.3% developing transient maternal tachycardia, 3.45% developing FHR variations and 1.15% had vomiting. Studies done by AH Khosla et al.,[8], K Devinder et al.,[1], K Tiwari et al.,[2] and JB Sharma et al.,[7] showed no major side effects with drotaverine and valethamate bromide. Transient maternal tachycardia was noted in 16% of cases receiving valethamate bromide in studies done by AH Khosla et al., and K Tewari et al.,. 28% of cases developed transient maternal tachycardia in study done by K Devinder et al.,.

CONCLUSION

Drotaverine is more effective than valethamate bromide in reducing the duration of active phase of labour. Rate of cervical dilatation is significantly higher in drotaverine group compared to the valethamate group. Women in the drotaverine group received less number of injections than women in valethamate group. No major maternal or fetal side effects were noted in both the groups.

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