

Comparison of Drotaverine and Epidosin in First Stage of Labor

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OBJECTIVE – To compare the efficacy of drotaverine and epidosin in shortening the duration of first stage of labor.

METHOD – Three hundred demographically similar women with full term pregnancy in active labor were included in the study and divided in two groups viz. drotaverine group (N=250) given drotaverine intramuscularly at 3-4 cm dilatation two hourly and epidosin group (N=50) were given epidosin intramuscularly at 3-4 cm dilatation one hourly. Maximum of three injections were given in both the groups. Comparative analysis was carried out as regards duration of various stages of labor, rate of cervical dilatation, side effects and fetomaternal outcome.

RESULTS – Duration of active phase of first stage was 116.34 ± 59.44 and 158.78 ± 58.98 minutes in group I and II respectively. Rate of cervical dilatation was 3.99 ± 2.21 and 2.74 ± 1.72 cm/hour in group I and II respectively. Difference between the values in both groups were statistically significant. Side effects were less in the drotaverine group. **CONCLUSION** – Drotaverine was observed to be a better drug for cervical dilatation than epidosin.

Key words : drotaverine, epidosin, cervical dilatation, labor

Introduction

Labor is a multifactorial process which involves myometrial contraction, cervical ripening and dilatation and the expulsion of the fetus and placenta in an orderly manner. The first stage of labor in a primigravida lasts about 12-16 hours and in a parous woman 6-8 hours.

Prolonged labor has been a dreaded problem for obstetricians. The most common cause of prolonged first stage of labor is cervical spasm leading to cervical dystocia. Spasmolytic drugs help to relieve cervical spasm and facilitate cervical dilatation during first stage of labor.

Many spasmolytic drugs have been used and tried in the past. Some of them caused side effects due to their anticholinergic properties and others caused tachycardia due to their effect on smooth muscle of vessel walls. Drotaverine is a newer spasmolytic drug which is claimed to reduce the duration of labor by accelerating cervical dilatation without causing side effects. It is an isoquinoline derivative (3', 4', 6, 7 – tetraethoxyl-1-benzal-1,2,3,4-tetrahydroisoquinoline), binds to surface of smooth muscles and changes their membrane potential and permeability. It is claimed to be safe with no side effects and no drug interactions. It inhibits phosphodiesterase IV enzyme which breaks cyclic AMP and cyclic GMP which play an important role in regulation of smooth muscle tone¹. Epidosin

(valemthamate bromide) is also an antispasmodic which helps in cervical dilatation due to its neurotropic or atropine like action and musculotropic or papaverine like action.

Material and Methods

Three hundred women at 37 to 41 weeks pregnancy with vertex presentation in established labor i.e. effective uterine contractions, good cervical effacement and cervical dilatation 3-4 cm, were included in the study irrespective of their parity. Women with previous uterine scar, malpresentation, multiple pregnancy, antepartum haemorrhage, cephalopelvic disproportion, pre-eclampsia and other pregnancy complications were excluded.

The selected women were divided into two groups :-

- I. Drotaverine group – 250 women. Drotaverine 40mg (2ml) was given intramuscularly at 3-4 cm dilatation of cervix and repeated two hourly for a maximum of three doses.
- II. Epidosin group-50 women. Epidosin 8mg (1ml) was given intramuscularly at 3-4 cm dilatation of cervix and repeated one hourly for a maximum of three doses.

There was no significant difference in the gravidity, mean age and mean duration of gestation in the two groups (Table I). Progress of labor and duration of various stages of labor was noted. Neonates were examined at birth and at 10 minutes for Apgar score.

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Table I: Age, Parity and Gestational Age

Parameters	Drotaverine Group-I	Epidosin group - II	p-value
No. of women	250	50	
Mean age (years)	24.97 ± 3.90	25.18 ± 4.08	>0.05 (insignificant)
Mean period of Gestation (weeks)	38.60 ± 1.06	38.86 ± 1.16	>0.05 (insignificant)
Primigravidas	92 (36.8%)	20 (40%)	>0.05 (insignificant)
Multigravidas	158 (63.2%)	30 (60.%)	>0.05 (insignificant)

Table II: Duration of Various Stages of Labor and Rate of Cervical Dilatation

Parameters	Drotaverine Group-I	Epidosin group-II	p-value
No. of women	250	50	
Mean duration of active Phase of first stage (min)	116.34 ± 59.45	158.78 ± 58.99	<0.001 (Significant)
First injection to delivery Interval (min)	149.82 ± 63.75	191.32 ± 60.47	<0.001 (Significant)
Rate of cervical dilatation (cm/hr)	3.99 ± 2.21	2.74 ± 1.72	<0.01 (Significant)
Mean duration of second Stage (min)	33.02 ± 12.09	31.46 ± 12.52	>0.05 (Insignificant)
Mean duration of Third stage (min)	8.08 ± 2.17	8.00 ± 2.148	>0.05 (Insignificant)

It was observed that mean duration of active phase of first stage of labor in Group I was 116.34 ± 59.45 minutes and in Group II 158.78 ± 58.99 minutes. Mean duration of first injection to delivery interval in Group I was 149.82 ± 63.75 minutes and in Group II 191.32 ± 60.47 minutes. Duration of active phase of first stage and injection to delivery interval were significantly shorter in the Drotaverine group ($p < 0.001$) (Table II).

Rate of cervical dilatation in Group I was 3.99 ± 2.21 cm/hour and in Group II 2.74 ± 1.72 cm/hour. Cervical dilatation was significantly faster in Group I ($p < 0.01$) (Table II).

Mean duration of second stage of labor in Group I (33.02 ± 12.09 minutes) and that in Group II (31.46 ± 12.52 minutes) were comparable. Mean duration of third stage of labor in Group I (8.08 ± 2.17 minutes) and that in Group II (8.00 ± 2.14 minutes) were comparable (Table II).

Drotaverine shortened the duration of active phase of first stage of labor in primigravidas by 20.2% and in multigravidas by 31.7% as compared to epidosin ($p = 0.1$). Rate of cervical dilatation in the drotaverine group was faster by 24.4% in primigravidas and by 32.2% in multigravidas when compared to the rates in ($p = 0.1$) epidosin group (Table III).

Table III : Duration of Active Phase of First Stage and Rate of Cervical Dilatation According to Gravidity

Gravidity	Group	No. of Women	Mean duration of active phase of 1 st stage (min.)	Difference of means		Mean rate of cervical dilatation in cm/hour	Difference of means	
				Minutes	Percent		Minutes	Percent
Primigravids	Drotaverine	92	143.91	36.4	20.2	3.18	0.77	24.4
	Epidosin	20	180.40			2.41		
Multigravids	Drotaverine	158	99.7	46.4	31.7	4.45	1.48	33.2
	Epidosin	30	146.6			2.97		

Table IV : Side Effects in Drotaverine and Epidosin Group

Side effects	Drotaverine group (Percentage)	Epidosin group (Percentage)	Value of 'p'
Headache	3.2	4.0	0.1
Dryness of mouth	-	10.0	
Tachycardia	4.0	28.0	0.001
Flushing of face	-	6.0	-

Side effects of epidosin like dryness of mouth and flushing of face were not seen in drotaverine group at all. Tachycardia was observed in 4% women in drotaverine group and in 28% women in epidosin group (Table IV).

No newborn in group I had Apgar score of ≤ 7 at birth while in group II 4% newborns had score of 7 at birth. All the newborns in both the groups had Apgar score of 9 at 5 minutes. No case of postpartum hemorrhage was observed in any woman.

Discussion

Suranyi² observed that drotaverine treated group showed significant shortening of injection delivery interval (mean 151 minutes) as compared to papaverine and placebo group. Injection delivery interval of 149.82 ± 63.7 minutes in the present study in the drotaverine group is comparable.

Demeter and Blasko³ observed that drotaverine shortens the dilatation stage of labor by 53 minutes (mean 183.6 ± 121.1 minutes) as compared to a control group. Duration of II and III stage were not prolonged. Drotaverine does not interfere with uterine contractility. Incidence of cervical tears was also significantly reduced in the

drotaverine group. In their study duration of dilatation stage was calculated from initiation of uterine contractions till full dilatation of cervix. In our study, we calculated active phase of first stage from the time when the cervix was 3-4 cm dilated to full dilatation of cervix. Hence values of duration of dilatation stage can not be compared.

Goswami et al⁴ compared drotaverine and epidosin as regards the effect on labor. They concluded that drotaverine shortens the duration of first stage by 2.8 hours as compared to a control group and it also hastens cervical dilatation by the rate of 1.3 to 2.04 cm per hour as compared to a control group. In our study, drotaverine hastened cervical dilatation by the rate of 0.77 cms/hour in primigravidas and by 1.48 cm/hour in multigravidas as compared to the epidosin group.

Drotaverine significantly shortened ($p < 0.001$) first injection to delivery interval (mean 149.82 ± 63.75 min.) as compared to epidosin (mean 191.32 ± 60.47 min.). Rate of cervical dilatation in the present study in primigravidas in the drotaverine group viz. 3.18 cm/hour is comparable to that reported by Goswami et al⁴ viz 2.71 ± 1.41 cm/hour.

Neither drug has any effect on second or third stage of labor as regards its duration or complications. Both smoothly dilate the cervix as no case of traumatic PPH was observed in either group. Incidence of side effects with drotaverine is significantly less than that with epidosin. All the above studies also concluded that incidence of side effects is less with drotaverine.

Drotaverine is a very safe, potent and effective drug to shorten first stage of labor without any maternal or fetal side effects. It is significantly better than epidosin and had less side effects.

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