

A Comparative Study of the Efficacy of Valethamate Bromide with Drotaverine in Normal Labor

Anju Huria Khosla, Indu Bala, Krishna Dahiya, Krishna Sangwan

Department of Obstetrics and Gynecology, Pt. B. D. Sharma PGIMS, Rohtak

OBJECTIVE - To study the effect of drugs like drotaverine and valethamate bromide on the duration of labor.

METHODS - A randomised prospective study was carried out on 300 women in normal labor. In the active phase of labor at 4 cm cervical dilatation, 100 women were given injection epidosisin 8 mg intramuscularly every 30 minutes for 3 doses, 100 women were given injection drotaverine hydrochloride 40 mg intramuscularly every 2 hours and 100 women (controls) were not given any drug. The duration of first, second and third stages of labor was noted.

RESULTS - The mean duration of first stage of labor was 132.67 ± 60.24 minutes in the epidosisin group, 175.92 ± 90.56 minutes in the drotaverine group and 287.68 ± 104.1 minutes in the control group. These differences were statistically significant. There was no difference in the duration of second and of third stages. The apgar of the neonates was normal in all groups and there was no side effect with drotaverine. Tachycardia flushing and dryness of mouth were seen in some patients with epidosisin. **CONCLUSION** - Both epidosisin and drotaverine were highly effective; epidosisin was better in multiparas.

Key words : labor, epidosisin, drotaverine

Introduction

In modern obstetrics O'Driscoll et al¹ founded the concept of active management of labor. The aim of active management is a reduction in the total duration of labor without causing any adverse effects on the mother or fetus.

Many times it is observed that inspite of good uterine contractions cervix fails to dilate or dilates very slowly. This is functional cervical dystocia. Methods that aim at minimising the incidence of functional cervical dystocia and cutting short the first stage of labor are welcome by both obstetricians and women.

A major breakthrough was achieved in the management of cervical dystocia with the introduction of Esocin by Steinman in 1953. Valethamate bromide (Epidosisin) is one of the drugs of this group. It is a potent, rapidly acting, cholinolytic spasmolytic and musculotropic agent. Efficacy of epidosisin in shortening the first stage of labor was reported by Desai et al². However various side effects like dryness of mouth, flushing of face and maternal tachycardia have been reported the use of this drug. Drotaverine, a benzylisoquinoline derivative is an effective spasmolytic drug. It acts by selective inhibition of phosphodiesterase type IV enzyme which is present in high concentration in myometrium near term, thus facilitating cervical dilatation during labor.

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Correspondence :

Dr. Anju Huria Khosla

H. No. 60, Sector-1, Urban Estate, Rohtak - 124 001.

Tel. 0091-1262 43791.

The present study was undertaken to analyse and compare the efficacy and safety of these two drugs in normal labor.

Material and Methods

This is a prospective study of 300 pregnant women between 38-41 weeks of gestation admitted in labor from June 2000 to August 2001 carried out to compare the efficacy and safety of intramuscular valethamate and drotaverine hydrochloride in active phase of normal labor.

Women having normal singleton pregnancy at 38-41 weeks gestation, with vertex presentation, intact membranes and spontaneous onset of labor were included in the study. Those with previous uterine scar, cephalopelvic disproportion grand multiparity, antepartum hemorrhage and twin pregnancy were excluded from the study.

The women were randomly assigned to group I, II and III. Group I (n=100) consisted of 100 women who were administered an injection of valethamate bromide (Epidosisin, TTK Pharma) 8mg every half hour for three doses intramuscularly. Group II consisted of 100 women who were administered an injection of drotaverine hydrochloride (Drotin, Martin and Harris Ltd.) 40 mg intramuscularly and repeated every 2 hours for a maximum of three injections. Group III (n=100) were not given any medication and acted as control. The three groups were matched for age, parity and cervical findings.

General physical examination, obstetric examination, and routine investigations were performed in all cases.

All the women were in active labor with well established uterine contractions and cervical dilatation of 4 cm with at least 50% cervical effacement. Progress of labor was plotted on partogram. Vaginal examination was repeated every 2 hours to assess progress of labor. Any side effects of the drugs, number of injection required, maternal complications and neonatal condition at birth were noted. The data was statistically analysed.

Results

The mean ages of women were 24.24, 23.03 and 23.64 years in Group I, II and III respectively. These differences were not significant statistically.

The majority of women viz. 68%, 66% and 65% in group I, II and III respectively were primigravidas. These differences were not significant statistically.

The period of gestation ranged between 38-41 weeks with mean of 39, 38.92 and 39.08 weeks in Group I, II and III respectively. These difference were not significant statistically.

The mean duration of first stage of labor after 4 cm dilatation was 132.64±60.24 minutes, 175.92±90.56 minutes and 287.68 ±104.10 minutes in Group I, II and III respectively. These differences were statistically significant. ($p < 0.001$ between group I and III and between Group II and III and $p < 0.01$ between Group I and II).

The duration of first stage in nulliparas after 4 cm dilatation was 145.94±62.08 minutes, 208.81±89.44 minutes and 318.27±93.66 minutes in Group I, II and III respectively while that in multiparas was 104.37±45.2 minutes, 112.05±49.81 minutes and 230.85±99.54 minutes in Group I, II and III respectively. Both valethamate and drotaverine caused highly significant reduction in duration of first stage as compared to that in controls in nulliparas as well as in multiparas ($p < 0.001$). Valethamate was significantly more effective than drotaverine in nulliparas ($p < 0.01$) but not so in multiparas (Table I).

Mean rate of cervical dilatation per hour was 2.71 cm 2.04 cm and 1.25 cm. Group I, II and III respectively. The differences were statistically significant ($p < 0.001$ for Group I and III, $p < 0.001$ for group II and III, $p < 0.01$ for Group I and II). There was no statistical significant difference in second and third stages of labor in the three groups.

Mode of delivery was vaginal in all the 300 women. Ventouse was required in three women in group I and in four women each in group II and III.

All the babies had good apgar scores and were discharged in good condition.

Forty patients in valethamate group had mild side effects in the form of tachycardia (16%), flushing of face (4%) and dryness of mouth (4%). None of the patients in drotaverine group had any side effects.

Table I : Parity and Duration of First Stage of Labor after 4cm Dilatation of the Cervix

Parity	Group I		Group II		Group III	
	No. of Women and Percentage	Mean duration after 4 cm dilatation (min.)	No. of women and percentage	Mean duration after 4 cm dilatation (min.)	No. of women and percentage	Mean duration after 4 cm dilatation (min.)
Nullipara	68(68%)	145.94±62.08	66(66%)	208.18±89.44	65(65%)	318.27±93.66
Multipara	32(32%)	104.37±45.23	34(34%)	112.05±49.81	35(35%)	230.85±99.64
'P' value between		Nullipara		Multipara		
Group I:II		<0.001		<0.001		
Group II:III		<0.001		<0.001		
Group I:II		<0.01		NS		

Discussion

Despite good uterine contractions, inhibitory impulses in the form of spasm often impair cervical dilatation and prolong the duration of labor. Any method which aids in reducing the tone of cervical musculature will certainly favour early dilatation of cervix and hasten labor.

Mukhopadhyay et al³, Sarin et al⁴, Purwar and Bulsara⁵ and Puri et al⁶ reported an almost 40% reduction in duration of labor with epidosisin as compared to controls. A similar reduction in duration of labor with drotaverine is also reported by Turi-Blasko⁷ and Mehrotra⁸.

Sharma et al⁹ have reported excellent results with drotaverine when compared to epidosisin. However, in our study, the rate of dilatation of cervix was slightly more with epidosisin as compared to drotaverine but drotaverine scored over its rival in having absolutely no side effects.

Both valethamate and drotaverine appear to be effective in acceleration of labor. Valethamate is more effective with minimal maternal side effects. Drotaverine is safe for both mother and fetus. There was no increase in instrumental deliveries with either.

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